

Adolescent Assent to Participate in a Research Study

Name of Study Volunteer

Screening and Brief Intervention for Suicidality and Nonsuicidal Self-Injury Among Youth in the Juvenile Justice System

Version 5; 02-25-20 RCT

KEY INFORMATION

You are invited to take part in a Brown University and Lifespan/Miriam Hospital research study. Your participation is voluntary.

- **PURPOSE:** We are trying to find new ways to better help court-involved teenagers who have thoughts of hurting themselves.
- **PROCEDURES:** You will be asked to complete questionnaires about your demographics, thoughts of wanting to hurt yourself, traumatic/violent experiences, substance use, peer and family relationships, and if you are interested in getting counseling. These surveys may be completed in person, on the phone, or via an emailed link. You will then be randomly chosen – by something like a flip of a coin - to either: 1) speak with a counselor about the results from the questionnaires you complete today and hard to control feelings/impulses and/or thoughts of wanting to hurt yourself today. This may happen in person, or via a zoom video-conferencing call. The counselor will call you in one week to check in on you; or 2) speak with a counselor about the results from the questionnaires you complete today and receive education about things that trigger emotional outbursts and/or thoughts hurting yourself. You may also be referred to talk to someone about your thoughts and feelings. In both cases, the session with the counselor will be audio recorded. Also, the research team will ask your permission provide the worker who referred you to the program with a summary of your performance on some of the questionnaires you complete at each session. You will complete some of the questionnaires again in one month and most of the questionnaires three months from now.
If your appointments are to be completed via phone or zoom video-conferencing, please ensure that you schedule the appointment for a time when you are able to answer questions in a private space.
- **TIME INVOLVED:** This study starts today and involves 2 more sessions, in 1 and 3 months from now. It will take up from 60 to 90 minutes of your time today and at 3 months, and about 20 minutes in 1 month.
- **COMPENSATION:** You will receive \$30 for your time in completing the interviews today, \$20 for completing the interviews in 1 month, and \$40 for completing the interviews 3 months from now (Total amount \$90). All compensation will be in the form of gift-cards. If the session is completed via phone or zoom, compensation will be mailed upon completion.
- **RISKS:** You may feel uncomfortable about the sensitive topics discussed and there is a chance of loss of privacy and confidentiality affecting your reputation, for example regarding substance use.
- **BENEFITS:** There are no direct benefits to you if you agree to be in this research study. However, you may learn some ways to help yourself cope with stress that may

make you think of injuring yourself.

- **ALTERNATIVES TO PARTICIPATION:** Your decision to participate in this study will not affect your case or any court proceedings. If you don't want to participate in this study, you can receive any care your worker decides is useful.

What will I be asked to do? Today, you will be asked to complete questionnaires about demographics, thoughts of wanting to hurt yourself, your interest in getting counseling for these thoughts, traumatic/violent experiences, general feelings/behaviors, thoughts on peers and family relationships, and substance use. Your parent will answer questions regarding obstacles to getting you to counseling, services you have received, satisfaction with those services, your family, and your and their mood and behavior. You will then be randomly chosen – by something like a flip of a coin - to either: 1) speak with a counselor about the results from the questionnaires you complete today and hard to control feelings/impulses and/or thoughts of wanting to hurt yourself today. The counselor will call you in one week to check in on you; or 2) speak with a counselor about the results from the questionnaires you complete today and receive education/handouts about things that trigger emotional outbursts and/or thoughts hurting yourself. You may also be referred to talk to someone about your thoughts and feelings. In both cases, the session with the counselor will be audio recorded. At the end of the meeting with you, the counselor will talk to you and your parent about what is the best way to help you right now. Today's session will take 60-90 minutes in total, depending on which group you are selected for. One month from today, we will follow up with you in person or over the phone and you will be asked to complete a few questionnaires about your general feelings, behaviors, and experiences, as well as thoughts of wanting to hurt yourself. This session should take about 20 minutes. In 3 months from now you and a parent will be asked to complete the same questionnaires that you will complete during your session today, except for demographics. If you are chosen for the second group, you will also have option meet with a counselor for 30 minutes to discuss hard to control emotions/impulses and/or any thoughts you may have of wanting to hurt yourself.

This should take 60-90 minutes, depending on which group you are selected for. These interviews can take place at the court, your home, or a public place like a local library (where we are able to meet in a private space). These sessions can happen in person, via phone, an emailed link, or via a zoom video conferencing call.

We will also collect information from your court file, including: information about your involvement with the Rhode Island Family Court, such as number of charges, types of past charges, and whether you receive any new charges during the course of the study. We will also collect information any mental health screening at the Rhode Island Family Court and previous mental health treatment referrals.

If you were to become detained or incarcerated at the Rhode Island Training School or another detention or correctional facility over the course of the study, your participation would be forfeited for the follow-up appointments that overlap with your incarceration.

Will I be paid? You will receive \$30 for answering questionnaires today, \$20 for answering the questionnaires in 1 month, and \$40 for answering the questionnaires in 3 months. If you complete all of these interviews, you will receive \$90 in total. If the session is completed via phone, zoom video call, or email, payment will be mailed following completion of the session.

TABLE 1.	All parents	All teens
Baseline Assessment [\$30]	<u>Parent assessment</u> (about 45 minutes) <ul style="list-style-type: none"> • Parent questionnaires on barriers to receiving counseling • Persons to contact if we cannot reach you (optional) 	<u>Teenager assessment</u> (about 45 minutes) <ul style="list-style-type: none"> • Adolescent questionnaire on thoughts about hurting oneself • Adolescent questionnaire on motivation for receiving treatment
Counseling session	Parents and Teens will be randomly selected to either: <ol style="list-style-type: none"> 1. Meet with a mental health counselor (30 minutes) receive education about things that trigger emotional outbursts and/or thoughts hurting yourself This session will be audio recorded. or 2. Meet with a mental health counselor (30 minutes) receive education/handouts about things that trigger emotional outbursts and/or thoughts hurting yourself. This session will be audio recorded. 	
1 Month Assessment [\$20]	<u>Parent assessment</u> (about 20 minutes): <ul style="list-style-type: none"> • Parent questionnaires on barriers to teen treatment, teen’s motivation for treatment, and family relationships. • Feedback questionnaire about intervention & counselor 	<u>Teenager assessment</u> (about 20 minutes): <ul style="list-style-type: none"> • Adolescent questionnaires on thoughts about hurting oneself, traumatic/violent experiences, and other feelings/behaviors. • Questionnaires on peer and family relationships, and motivation for treatment • Feedback questionnaire about intervention & counselor
3 Month Assessment [\$40]	Parents and teens complete questionnaires about what services they received in the community, how satisfied they were with those services, and their family (about 20 minutes). Parents complete a questionnaire about obstacles to receiving treatment, as well as teen and self-report behavioral symptoms (about 15 minutes); teens complete questionnaires about thoughts of hurting oneself, traumatic/violent experiences, general feelings/behaviors, and substance-use (20 minutes). [If group 2:] You have the option to meet with a mental health counselor (30 minutes) to discuss hard to control feelings/impulses and/or thoughts of wanting to hurt yourself today.	

What are the benefits? There may be no benefits to participating in this study. There is a possibility that participating in this research study may positively affect your relationship with Rhode Island Family Court by satisfying the Probation Officer’s concerns that you should Receive further mental health evaluation. However, this cannot be guaranteed and the same

positive effect may occur by arranging for further mental health evaluation outside of being in this study.

What are the risks? The interview and questionnaires that we use in this study have been completed by other teenagers who have been involved in the courts. You will be asked questions of a sensitive nature about your mental health, substance use, traumatic/violent experiences, etc. When you are answering the questions, you may sometimes feel upset or experience emotional distress. You can refuse to answer any questions you do not like. You can also stop your participation in the study at any time. There is also a risk of loss of privacy regarding your sensitive mental health and substance use information – the information you share with us could affect your reputation and employability and could lead to negative legal consequences if it were disclosed with people outside of the study. Refer to the following section for more information on the risk of loss of privacy.

How will my information be protected? All of your records from this study will be treated as private records. The records will be protected according to the rules of Brown University. Your name will not be on the questionnaires. Records will be kept in a locked filing cabinet in a locked office at Brown University. Only researchers working on this study will have access to the information provided by you.

All laptop computer data as well as any paper data that is entered into a computer database will be accessible only to research staff members and will be password protected. All paper data will be stored in locked file cabinets behind locked doors and will only be accessible to research staff members. Only research staff who have direct contact with you will have access to your identity.

In this study we will be audio recording the counseling sessions. We will use a digital recorder. We will keep this information confidential. We will keep the information we collect about you, including audio recordings, during the research for study record keeping. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you. At the end of the study, audio tapes will be destroyed. We may use or share your research information for future research studies (excluding audio tapes), but it will be deidentified, which means it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional consent for these studies. We may also share your deidentified information with other researchers here, or at other institutions in the United States or around the world.

Brown University and Lifespan/Miriam Hospital staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

We will not disclose details regarding your answers to your parent or the court. However, your Probation Officer or worker will know you are in the study. To further keep others from learning about your participation in this study, we have gotten a Certificate of Confidentiality from the federal agency giving us money for this study. With this certificate, the research team cannot be forced to tell (even if the court orders us to do so) any information that would identify you or your parent. However, if you report you are actively suicidal, or plan to hurt someone else, we will tell your parents and get you help by telling appropriate authorities and taking appropriate medical action. In a situation that we are worried about your safety, the research team may have to tell someone that you and your parent were research participants in this study. Also, if

you report that you have been sexually abused, physically abused, or neglected by a parent/guardian or caretaker, we may have to report this information to the Department of Children, Youth, and Families (DCYF).

The information you share with us can still be requested by the National Institute of Health (NIH) for the purposes of auditing or program evaluation of NIH-funded projects. You 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.

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 website at any time.

What if I want to stop? If you do not want to be in the study, it is OK to say no. Your Probation Officer or worker will tell you what other services will be provided by the courts. Your parent will not be told that you said no. You can stop being in the study any time you want to, and nobody will be upset with you. Your decision to participate in this study will not affect your case or any court proceedings. Your decision to participate in this study will not impact your current or future relationships with Brown University or Lifespan.

Who can I talk to if I have questions about this study? If you have any questions about this study, you can contact Dr. Anthony Spirito at (401) 444-1929 or Anthony_Spirito@brown.edu.

Who can I talk to if I have questions about my rights as a participant? If you have any complaints or questions about being in the project, you can call the Brown University Human Research Protection Program at (401) 863-3050 or toll-free at (866) 309-2095 or email Brown's HRPP at IRB@brown.edu.

Your mom, dad, and/or guardian know about this study, and they think it is OK for you to participate. If you want to be in this study, you can tell the research staff member and sign this form.

You will be offered a copy of this form.

_____ Verbal assent [Audio recording of consent may be found on Stronghold - DPHB: Safety]

Teen's Signature and Date / PRINTED NAME

Research Staff Signature and Date / PRINTED NAME

BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION:
Parent Consent for Self and Teen Form

Name of Study Volunteer

Screening and Brief Intervention for Suicidality and Nonsuicidal Self-Injury Among Youth in the Juvenile Justice System

Version 5; 02-25-20 RCT

KEY INFORMATION

You and your teen are invited to take part in a Brown University and Lifespan/Miriam Hospital research study. Your participation is voluntary.

- **PURPOSE:** We are trying to figure out new ways to better help court-involved teenagers who report having thoughts of hurting themselves.
- **PROCEDURES:** Your teen will be asked to complete questionnaires about their demographics, their thoughts of wanting to hurt themselves, traumatic/violent experiences, substance use, peer and family relationships, and if they are interested in getting counseling. These surveys may be completed in person, on the phone, or via an emailed link. They will complete some of these questionnaires again in one month and all of the questionnaires except for demographics three months from now. You and your teen will also be randomly assigned – by something like the flip of a coin – to either: 1) have your teen meet with a counselor about hard to control emotions/impulses and/or their thoughts of wanting to hurt themselves, today. The counselor will follow-up in one-week time to check in on you and your teen; or 2) have your teen speak with a counselor about the results from the questionnaires you complete today and receive education about things that trigger emotional outbursts and/or thoughts hurting yourself. You may also be referred to talk to someone about your thoughts and feelings. This may happen in person, or via a zoom video-conferencing call. In both cases, the session with the counselor will be audio recorded. Also, the research team will ask your permission provide the worker who referred you to the program with a summary of your performance on some of the questionnaires you complete at each session. You will be asked to complete questionnaires today on demographics, services used, satisfaction with those services, family relationships, and your and your teen's mood and behavior. In one- and 3-months' time you will be asked to complete these questionnaires again, with the exception of demographics.
If your appointments are to be completed via phone or zoom video-conferencing, please ensure that you schedule the appointment for a time when you are able to answer questions in a private space.
- **TIME INVOLVED:** This study starts today and involves 2 more sessions, in 1 and 3 months from now. It will take you and your teen 60-90 minutes of your time today and in 3 months, and about 20 minutes of your and your teen's time in 1 month.
- **COMPENSATION:** You and your teen can each earn up to \$90 for your participation. All compensation will be in the form of gift-cards. If the session is completed via phone or zoom, compensation will be mailed upon completion.
- **RISKS:** You and your teen may feel uncomfortable about the sensitive topics

discussed and there is a chance of loss of privacy and confidentiality affecting your reputation.

- **BENEFITS:** There are no direct benefits to you or your teen if you agree to be in this research study. However, your teen may learn some ways to help cope with stressful thoughts.

1, Researcher: This research is being conducted by Anthony Spirito, PhD at Brown University,

TABLE 1.	All parents	All teens
Baseline Assessment [\$30]	<u>Parent assessment</u> (about 45 minutes) <ul style="list-style-type: none"> • Demographics • Parent questionnaires on barriers to receiving counseling, services you've received, satisfaction with those services, your family, your and your teen's mood and behavior • Persons to contact if we cannot reach you (optional) 	<u>Teenager assessment</u> (about 45 minutes) <ul style="list-style-type: none"> • Demographics • Adolescent questionnaire on thoughts about hurting self, traumatic/violent experiences, and other feelings/behaviors • Adolescent questionnaires on substance use • Adolescent questionnaires on peer and family relationships • Adolescent questionnaires on motivation for receiving treatment
Counseling session	Parents and Teens will be randomly selected to either: <ol style="list-style-type: none"> 1. Meet with a mental health counselor (30 minutes) receive education about things that trigger emotional outbursts and/or thoughts hurting yourself This session will be audio recorded. <li style="text-align: center;"><u>or</u> 2. Meet with a mental health counselor (30 minutes) receive education/handouts about things that trigger emotional outbursts and/or thoughts hurting yourself. This session will be audio recorded. 	
1-Month Assessment [\$20]	<u>Parent assessment</u> (about 20 minutes): <ul style="list-style-type: none"> • Parent questionnaires on barriers to teen treatment, teen's motivation for treatment, and family relationships. • Feedback questionnaire on intervention and counseling 	<u>Teenager assessment</u> (about 20 minutes): <ul style="list-style-type: none"> • Adolescent questionnaires on thoughts about hurting oneself, traumatic/violent experiences, and other feelings/behaviors. • Questionnaires on peer and family relationships, and motivation for treatment • Feedback questionnaire on intervention and counseling.
3 Month Assessment [\$40]	Parents and teens complete questionnaires about what services they received in the community and how satisfied they were with those services, and family dynamics (about 20 minutes). Parents complete a questionnaire about obstacles to receiving treatment, as well as teen and self-report behavioral symptoms (about 15 minutes); teens complete questionnaires about thoughts of hurting oneself, traumatic/violent experiences, general feelings/behaviors, and substance use (20 minutes). <p>[If group 2:] You have the option to have your teen meet with a mental health counselor (30 minutes) to discuss hard to control feelings/impulses and/or thoughts of wanting to hurt yourself today.</p>	

and Kathleen Kemp, PhD at Miriam Hospital. Dr. Spirito may be contacted at anthony_spirito@brown.edu or 401-444-1929. Dr. Kemp may be contacted at Kathleen_kemp@brown.edu or 401-793-8269.

2. What is the study about? We are trying to figure out new ways to better help court-involved teenagers who report having hard to control emotions/impulses and/or thoughts of hurting themselves.

What will I be asked to do? Today, your teen will be asked to complete a questionnaire about their demographics, thoughts of wanting to hurt themselves as well as traumatic/violent experiences, general feelings/behaviors, thoughts about getting counseling help, thoughts on their peers and other relationships, and substance use. You will complete a form about your demographics, obstacles to getting counseling for your teen, services you have received, satisfaction with those services, your family, and your and your teen's mood and behavior.

After completing the questionnaires, you and your teen will then be randomly assigned – by something like a flip of a coin - to either: 1) have your teen speak with a counselor about the results from the questionnaires you complete today and hard to control feelings/impulses and/or thoughts of wanting to hurt yourself today. The counselor will call you in one week to check in on you; or 2) have your teen speak with a counselor about the results from the questionnaires you complete today and receive education/handouts about things that trigger emotional outbursts and/or thoughts hurting yourself. Your teen may also be referred to talk to someone about your thoughts and feelings. In both cases, the session with the counselor will be audio recorded. The assessment and counseling session (whether it is today or in 3 months' time) will take 60-90 minutes in total. This session can happen in person, via phone, an emailed link, or via a zoom video conferencing call.

In 1 and 3 months from now, you and your teen will be asked to complete some of the questionnaires you completed today, again. The one-month appointment should take about 20 minutes of your time, the 3-month appointment should take 60-90 minutes. If you are chosen for the second group, your teen will also have option meet with a counselor for 30 minutes to discuss hard to control emotions/impulses and/or any thoughts he/she may have of wanting to hurt themselves. These sessions can happen in person, via phone, an emailed link, or via a zoom video conferencing call.

We will also collect information from your teen's court file, including: information about your involvement with the Rhode Island Family Court, such as number of charges, types of past charges, and whether your teen receives any new charges during the course of the study. We will also collect any information on mental health screening at the Rhode Island Family Court and previous mental health treatment referrals if this information is in your court record.

If your child were to become detained or incarcerated at the Rhode Island Training School or another detention or correctional facility over the course of the study, their participation would be forfeited for the follow-up appointments that overlap with their incarceration.

3. Will we be paid? You and your teen will each receive \$30 for answering the questionnaires today. In 1 month time, you and your teen will each receive \$20 for completing the second session. In 3 months' time, you each will receive \$40 for completing the third session. If you complete all of these interviews, you each will receive \$90 in total. If you leave the study early or if we have to

take you out of the study you will only be given compensation for the visits you've completed. If the session is completed via phone, zoom video call, or email, payment will be mailed following completion of the session.

4. What are the risks? The interview and questionnaires that your teen will complete during this study have been completed by other teenagers who have been involved in the courts. In this study we will be asking your teen about their general feelings and behaviors, suicidal thoughts and behaviors, traumatic/violent experiences, and substance use. Some of these questions may make your teen feel uncomfortable or bring up unpleasant feelings or memories. Your teen can refuse to answer any questions they do not like. Your teen can also stop their participation in the study at any time. The questionnaires you will be answering will ask your own mental health and personal experiences which may cause you some discomfort. You can refuse to answer any questions you do not like. You can also stop your participation in the study at any time. There is a risk of loss of privacy in this study including sensitive information on your or your teen's emotional state and your teen's substance use. The information you and your teen share with us could affect your and their reputation and employability and could lead to negative legal consequences if it were disclosed with people outside of the study. Please refer to the section entitled "How will our information be protected?" for further information on the risk of loss of privacy.

5. What are the benefits? There may be no benefits to participating in this study. There is a possibility that participating in this research study may positively affect your relationship with Rhode Island Family Court by satisfying the Probation Officer's or worker's concerns that your teen should receive further mental health evaluation. However, this cannot be guaranteed and the same positive effect may occur by arranging for further mental health evaluation outside of being in this study.

6. How will my information be protected? All of your and your teen's records from this study will be treated as private records. The records will be protected according to the rules of Brown University. Your and your teen's names will not be on the questionnaires. Records will be kept in a locked filing cabinet in a locked office at Brown University. Only researchers working on this study will have access to the information provided by you.

All laptop computer data as well as any paper data that is entered into a computer database will be accessible only to research staff members and will be password protected. All paper data will be stored in locked file cabinets behind locked doors and will only be accessible to research staff members. Only research staff who have direct contact with you and your teen will have access to your identities.

In this study we will be audio recording the counseling sessions. We will use a digital recorder. We will keep this information confidential. We will store it for the duration of the study on a secure, encrypted database. At the end of the study, we will destroy the recordings.

We will keep the information we collect about you and your teen during the research, including audio tapes, for study record keeping. Your and your teen's names and other information that can directly identify you will be stored securely and separately from the research information we collected from you. Audio tapes will be destroyed at the end of the study. We may use or share your and your teen's research information for future research studies (excluding audio tapes), but it will be deidentified, which means that it will not

contain your names or other information that can directly identify you or your teen. This research may be similar to this study or completely different. We will not ask for your or your teen's additional informed consent for these studies. We may also share your and your teen's deidentified information with other researchers here, at other institutions in the United States or around the world.

Brown University and Lifespan/Miriam Hospital staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

We will not disclose details regarding your answers to your teen or the court. However, your teen's Probation Officer or worker will know if you agreed to participate in the study. Also, if your teen reports they are actively suicidal, or plans to hurt someone else, we will get your teen help by telling appropriate authorities and taking appropriate medical action. In a situation that we are worried about your teen's safety, the research team may have to tell someone that your teen was a research participant in this study. Also, if your teen reports that they have been sexually abused, physically abused, or neglected by a parent/guardian or caretaker, we may have to report this information to the Department of Children, Youth, and Families (DCYF).

To help us protect your privacy, we have obtained a certificate of confidentiality from the National Institutes of Health (NIH). The researchers can use the Certificate to legally 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. The information you share with us can still be requested by the National Institute of Health for the purposes of auditing. You 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. The Certificate of Confidentiality will not be used to prevent disclosure to the state or local authorities of such as child abuse and neglect, or harm to self or others.

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 Web site will include a summary of the results. You can search this Web site at any time.

7. Are there any alternatives to this study?

If you or your teen don't want to participate in this study, your teen can receive any care their Probation Officer or worker decides is useful.

8. What if we want to stop? If you do not want you or your teen to be in the study, it is OK to say no. You or your teen can stop being in the study any time you want to; your teen's decision to participate in this study will not affect your teen's case or any court proceedings. You and your teen's decisions to participate in this study will not impact your or your teen's current or future relationships with Brown University or Lifespan.

9. Who can I talk to if I have questions about this study? If you have any questions about this study, you can contact Dr. Anthony Spirito at (401) 444-1929 or Anthony_Spirito@Brown.edu.

10. Who can I talk to if I have questions about my rights as a participant? If you have any

complaints or questions about being in the project, you can call the Brown University Human Research Protection Program at (401) 863-3050 or toll-free at (866) 309-2095 or email at IRB@brown.edu. If English is not your first language the HRPP will find someone who is able to speak with you.

National Institute of Mental Health Data Archive (NDA)

Data from this study, including information about your teen, may be submitted to the NDA, a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code. With an easier way to share, researchers hope to learn new and important things about mental illnesses.

During and after the study, the researchers will send deidentified information about your teen's health and behavior to NDA. Other researchers nationwide can then apply to the NIMH to obtain access to your teen's deidentified study data for research purposes.

Although only your teen's deidentified data will be shared with other researchers requesting access through the NDA, specific identifying information is required by the NDA in order to assign a Global Unique Identifier (GUID) to your teen. This information includes your teen's full name, biological sex, date of birth, and city/state of birth. We will collect this information from you by having you complete an NDA Information Form, if you agree to share your teen's data with the NDA. This information will be submitted to the NIMH via the NDA, and your teen will have a GUID assigned to them and linked only to their identity. NIMH is the only entity that will have access to your teen's identifying information, which will be stored in the NDA GUID database. Once your teen has a GUID within the NDA system, any data collected from your teen in future studies that use the NDA can be linked to the data that we share from this study.

Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to privacy, and they will not share your teen's identity. The NDA also has a Certificate of Confidentiality to protect your teen's privacy, and that document will not waive any of the protections of the Certificate of Confidentiality granted for this study.

You and your teen may not benefit directly from allowing your teen's information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about data your teen contributed to NDA.

You may decide now or later that you do not want to share your teen's information using NDA. If you decide in the future that you do not want your teen's information included in the NDA, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. NDA information is available on-line at <https://data-archive.nimh.nih.gov>.

_____ Please initial here to choose to submit your information in the NDA

Please initial below if you would like to be contacted by our research team for future studies should you/your teen be eligible. This will allow us to contact you if other research opportunities become available, and you can make a decision at that time if you would like to participate.

_____ I would like to be contacted for future research studies

Your signature below or verbal consent shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

_____ Verbal consent [Audio recording of consent may be found on Stronghold – DPHB: Safety]

Teen's Name – Printed

Participant's Signature and Date

/

PRINTED NAME

Research Staff Signature and Date

/

PRINTED NAME



BROWN

BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION
(18 year old participants)

Screening and Brief Intervention for Suicidality and Nonsuicidal Self-Injury
Among Youth in the Juvenile Justice System
[Version 2, 2-25-20]

KEY INFORMATION:

You are invited to take part in a Brown University research study. Your participation is voluntary.

- **PURPOSE:** We are trying to find new ways to better help court-involved teenagers who have thoughts of hurting themselves.
- **PROCEDURES:** You will be asked to complete questionnaires about your demographics, thoughts of wanting to hurt yourself, traumatic/violent experiences, substance use, peer and family relationships, and if you are interested in getting counseling. These surveys may be completed in person, on the phone, or via an emailed link. You will then be randomly chosen – by something like a flip of a coin – to either:
1) speak with a counselor about the results from the questionnaires you complete today and hard to control feelings/impulses and/or thoughts of wanting to hurt yourself today. The counselor will call you in one week to check in on you; or 2) speak with a counselor about the results from the questionnaires you complete today and receive education about things that trigger emotional outbursts and/or thoughts hurting yourself. This may happen in person, via phone, or via a zoom video-conferencing call. You may also be referred to talk to someone about your thoughts and feelings. In both cases, the session with the counselor will be audio recorded. Also, the research team will ask your permission provide the worker who referred you to the program with a summary of your performance on some of the questionnaires you complete at each session. You will complete some of the questionnaires again in one month and most of the questionnaires three months from now.

If your appointments are to be completed via phone or zoom video-conferencing, please ensure that you schedule the appointment for a time when you are able to answer questions in a private space.

- **TIME INVOLVED:** This study starts today and involves 2 more sessions, in 1 and 3 months from now. It will take up from 60 to 90 minutes of your time today and at 3 months, and about 20 minutes in 1 month.



- **COMPENSATION:** You will receive \$30 for your time in completing the interviews today, \$20 for completing the interviews in 1 month, and \$40 for completing the interviews 3 months from now (Total amount \$90). All compensation will be in the form of gift-cards. If the session is completed via phone or zoom, compensation will be mailed upon completion.
- **RISKS:** You may feel uncomfortable about the sensitive topics discussed and there is a chance of loss of privacy and confidentiality affecting your reputation, for example regarding substance use.
- **BENEFITS:** There are no direct benefits to you if you agree to be in this research study. However, you may learn some ways to help yourself cope with stress that may make you think of injuring yourself.
- **ALTERNATIVES TO PARTICIPATION:** Your decision to participate in this study will not affect your case or any court proceedings. If you don't want to participate in this study, you can receive any care your worker decides is useful.

1. Researcher(s):

This research is being conducted by Anthony Spirito, PhD at Brown University, and Kathleen Kemp, PhD at Miriam Hospital. Dr. Spirito may be contacted at anthony_spirito@brown.edu or 401-444-1929. Dr. Kemp may be contacted at Kathleen_kemp@brown.edu or 401-793-8269.

2. What is this study about?

We are trying to figure out new ways to better help court-involved teenagers who report having hard to control emotions/impulses and/or thoughts of hurting themselves.

3. What will I be asked to do?

Today, you will be asked to complete a questionnaire about your demographics, thoughts of wanting to hurt yourself as well as traumatic/violent experiences, general feelings/behaviors, thoughts about getting counseling help, thoughts on your peers and other relationships, and substance use. Your parent will answer questions regarding obstacles to getting you to counseling, services you have received, satisfaction with those services, your family, and your and their mood and behavior.

After completing the questionnaires, you and your parent will then be randomly assigned – by something like a flip of a coin - to either: 1) have you speak with a counselor about the results from the questionnaires you complete today and hard to control feelings/impulses and/or thoughts of wanting to hurt yourself today. The counselor will call you in one week to check in on you; or 2) have you speak with a counselor about the results from the questionnaires you complete today and receive education/handouts about things that trigger emotional outbursts and/or thoughts hurting yourself. You may also be referred to talk to



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someone about your thoughts and feelings. In both cases, the session with the counselor will be audio recorded. At the end of the meeting with you, the counselor will talk to you and your parent about what is the best way to help you right now. The assessment and counseling session (whether it is today or in 3 months' time) will take 60-90 minutes in total. This session can happen in person, via phone, an emailed link, or via a zoom video conferencing call.

In 1 and 3 months from now, you and your parent will be asked to complete some of the questionnaires you completed today, again. One month from today, we will follow up with you in person or over the phone and you will be asked to complete a few questionnaires about your general feelings, behaviors, and experiences, as well as thoughts of wanting to hurt yourself. This session should take about 20 minutes. In 3 months from now you and a parent will be asked to complete the same questionnaires that you will complete during your session today, except for demographics. If you are chosen for the second group, you will also have option meet with a counselor for 30 minutes to discuss hard to control emotions/impulses and/or any thoughts you may have of wanting to hurt yourself. This should take 60-90 minutes, depending on which group you are selected for. These interviews can take place at the court, your home, or a public place like a local library (where we are able to meet in a private space). They may take place in person, via phone, or via a zoom conferencing call.

We will also collect information from your court file, including: information about your involvement with the Rhode Island Family Court, such as number of charges, types of past charges, and whether your teen receives any new charges during the course of the study. We will also collect any information on mental health screening at the Rhode Island Family Court and previous mental health treatment referrals if this information is in your court record.

If you were to become detained or incarcerated at the Rhode Island Training School or another detention or correctional facility over the course of the study, your participation would be forfeited for the follow-up appointments that overlap with your incarceration.

4. Will I be paid?

You will receive \$30 for answering questionnaires today, \$20 for answering the questionnaires in 1 month, and \$40 for answering the questionnaires in 3 months. If you complete all of these interviews, you will receive \$90 in total. If the session is completed via phone, zoom video call, or email, payment will be mailed following completion of the session.



TABLE 1.	All parents	All teens
Baseline Assessment [\$30]	<u>Parent assessment</u> (about 45 minutes) <ul style="list-style-type: none"> • Demographics • Parent questionnaires on barriers to receiving counseling, services you've received, satisfaction with those services, your family, your and your teen's mood and behavior • Persons to contact if we cannot reach you (optional) 	<u>Teenager assessment</u> (about 45 minutes) <ul style="list-style-type: none"> • Demographics • Adolescent questionnaire on thoughts about hurting self, traumatic/violent experiences, and other feelings/behaviors • Adolescent questionnaires on substance use • Adolescent questionnaires on peer and family relationships • Adolescent questionnaires on motivation for receiving treatment
Counseling session	Parents and Teens will be randomly selected to either: <ol style="list-style-type: none"> 1. Meet with a mental health counselor (30 minutes receive education about things that trigger emotional outbursts and/or thoughts hurting yourself This session will be audio recorded. or 2. Meet with a mental health counselor (30 minutes) receive education/handouts about things that trigger emotional outbursts and/or thoughts hurting yourself. This session will be audio recorded. 	
1-Month Assessment [\$20]	<u>Parent assessment</u> (about 20 minutes): <ul style="list-style-type: none"> • Parent questionnaires on barriers to teen treatment, teen's motivation for treatment, and family relationships. • Feedback questionnaire on intervention and counseling 	<u>Teenager assessment</u> (about 20 minutes): <ul style="list-style-type: none"> • Adolescent questionnaires on thoughts about hurting oneself, traumatic/violent experiences, and other feelings/behaviors. • Questionnaires on peer and family relationships, and motivation for treatment • Feedback questionnaire on intervention and counseling.
3 Month Assessment [\$40]	Parents and teens complete questionnaires about what services they received in the community and how satisfied they were with those services, and family dynamics (about 20 minutes). Parents complete a questionnaire about obstacles to receiving treatment, as well as teen and self-report behavioral symptoms (about 15 minutes); teens complete questionnaires about thoughts of hurting oneself, traumatic/violent experiences, general feelings/behaviors, and substance use (20 minutes). <p>[If group 2:] You have the option to have your teen meet with a mental health counselor (30 minutes) to discuss hard to control feelings/impulses and/or thoughts of wanting to hurt yourself today.</p>	



5. What are the risks?

The interview and questionnaires that we use in this study have been completed by other teenagers who have been involved in the courts. You will be asked questions of a sensitive nature about your mental health, substance use, traumatic/violent experiences, etc. When you are answering the questions, you may sometimes feel upset or experience emotional distress. You can refuse to answer any questions you do not like. You can also stop your participation in the study at any time. There is also a risk of loss of privacy regarding your sensitive mental health and substance use information – the information you share with us could affect your reputation and employability and could lead to negative legal consequences if it were disclosed with people outside of the study. Refer to the section entitled “How will my information be protected?” for more information on the risk of loss of privacy.

6. What are the benefits?

There may be no benefits to participating in this study. There is a possibility that participating in this research study may positively affect your relationship with Rhode Island Family Court by satisfying the Probation Officer’s concerns that you should receive further mental health evaluation. However, this cannot be guaranteed and the same positive effect may occur by arranging for further mental health evaluation outside of being in this study.

7. How will my information be protected?

All of your records from this study will be treated as private records. The records will be protected according to the rules of Brown University. Your name will not be on the questionnaires. Records will be kept in a locked filing cabinet in a locked office at Brown University. Only researchers working on this study will have access to the information provided by you.

All laptop computer data as well as any paper data that is entered into a computer database will be accessible only to research staff members and will be password protected. All paper data will be stored in locked file cabinets behind locked doors and will only be accessible to research staff members. Only research staff who have direct contact with you will have access to your identity.

In this study we will be audio recording the counseling sessions. We will use a digital recorder. We will keep this information confidential. We will keep the information we collect about you, including audio recordings, during the research for study record keeping. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you. At the end of the study, audio tapes will be destroyed. We may use or share your research information for future research studies (excluding audio tapes), but it will be deidentified, which means it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional consent for



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these studies. We may also share your deidentified information with other researchers here, or at other institutions in the United States or around the world.

Brown University and Lifespan/Miriam Hospital staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

We will not disclose details regarding your answers to your parent or the court. However, your Probation Officer or worker will know you are in the study. Also, if you report you are actively suicidal, or plan to hurt someone else, we will get you help by telling appropriate authorities and taking appropriate medical action. In a situation that we are worried about your safety, the research team may have to tell someone that you were a research participant in this study.

To help us protect your privacy, we have obtained a certificate of confidentiality from the National Institutes of Health (NIH). The researchers can use the Certificate to legally 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. The information you share with us can still be requested by the National Institute of Health for the purposes of auditing. You 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. The Certificate of Confidentiality will not be used to prevent disclosure to the state or local authorities of such as child abuse and neglect, or harm to self or others.

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 website at any time.

8. Are there any alternatives to this study?

If you don't want to participate in this study, you can receive any care their Probation Officer or worker decides is useful.

9. What if I want to stop?

You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time. Your decision to participate in this study will not affect your case or any court proceedings.



If you refuse to participate in or leave the study, your current or future relationship with Brown University or Lifespan will not be affected.

10. Who can I talk to if I have questions about this study?

If you have any questions about this study, you can contact Dr. Anthony Spirito at (401) 444-1929 or Anthony_Spirito@Brown.edu.

11. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu. If English is not your first language the HRPP will find someone who is able to speak with you.

12. National Institute of Mental Health Data Archive (NDA)

Data from this study, including information about you, may be submitted to the NDA, a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code. With an easier way to share, researchers hope to learn new and important things about mental illnesses.

During and after the study, the researchers will send deidentified information about your health and behavior to NDA. Other researchers nationwide can then apply to the NIMH to obtain access to your deidentified study data for research purposes.

Although only your deidentified data will be shared with other researchers requesting access through the NDA, specific identifying information is required by the NDA in order to assign a Global Unique Identifier (GUID) to you. This information includes your full name, biological sex, date of birth, and city/state of birth. We will collect this information from you by having you complete an NDA Information Form, if you agree to share your data with the NDA. This information will be submitted to the NIMH via the NDA, and you will have a GUID assigned to you and linked only to your identity. NIMH is the only entity that will have access to your identifying information, which will be stored in the NDA GUID database. Once you have a GUID within the NDA system, any data collected from you in future studies that use the NDA can be linked to the data that we share from this study.

Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to privacy, and they will not share your identity. The NDA also has a Certificate of Confidentiality to protect your



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privacy, and that document will not waive any of the protections of the Certificate of Confidentiality granted for this study.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If you decide in the future that you do not want your information included in the NDA, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. NDA information is available on-line at <https://data-archive.nimh.nih.gov>.

_____ Please initial here to choose to submit your information in the NDA

Please initial below if you would like to be contacted by our research team for future studies should you be eligible. This will allow us to contact you if other research opportunities become available, and you can make a decision at that time if you would like to participate.

_____ I would like to be contacted for future research studies

13. Consent to Participate

Your signature below or verbal consent shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

_____ Verbal consent [Audio recording of consent may be found on Stronghold – DPHB: Safety]

Participant's Signature and Date

/

PRINTED NAME

Research Staff Signature and Date

/

PRINTED NAME



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CONSENT FOR RESEARCH PARTICIPATION
(Parent for Self w/ 18 year old teen)

Screening and Brief Intervention for Suicidality and Nonsuicidal Self-Injury
Among Youth in the Juvenile Justice System
[Version 2; 2-25-2020]

KEY INFORMATION:

You are invited to take part in a Brown University research study with your teen. Your participation is voluntary. Your teen will separately provide consent for their participation.

- **PURPOSE:** We are trying to find new ways to better help court-involved teenagers who have thoughts of hurting themselves.
- **PROCEDURES:** Your teen will be asked to complete questionnaires about their demographics, their thoughts of wanting to hurt themselves, traumatic/violent experiences, substance use, peer and family relationships, and if they are interested in getting counseling. These surveys may be completed in person, on the phone, or via an emailed link. They will complete some of these questionnaires again in one month and all of the questionnaires except for demographics three months from now. You and your teen will also be randomly assigned – by something like the flip of a coin – to either: 1) have your teen meet with a counselor about hard to control emotions/impulses and/or their thoughts of wanting to hurt themselves, today. The counselor will follow-up in one-week time to check in on you and your teen; or 2) have your teen speak with a counselor about the results from the questionnaires you complete today and receive education about things that trigger emotional outbursts and/or thoughts of hurting yourself. You may also be referred to talk to someone about your thoughts and feelings. This may happen in person, via phone, or via a zoom video-conferencing call. In both cases, the session with the counselor will be audio recorded. Also, the research team will ask your permission provide the worker who referred you to the program with a summary of your performance on some of the questionnaires you complete at each session. You will be asked to complete questionnaires today on demographics, services used, satisfaction with those services, family relationships, and your and your teen’s mood and behavior. In one- and 3-months’ time you will be asked to complete these questionnaires again, with the exception of demographics.

If your appointments are to be completed via phone or zoom video-conferencing, please ensure that you schedule the appointment for a time when you are able to answer questions in a private space.



- **TIME INVOLVED:** It will take you and your teen 60-90 minutes of your time today and in 3 months, and about 20 minutes of your and your teen’s time in 1 month.
- **COMPENSATION:** You and your teen can each earn up to \$90 for your participation. All compensation will be in the form of gift-cards. If the session is completed via phone or zoom, compensation will be mailed upon completion.
- **RISKS:** You may feel uncomfortable about the sensitive topics discussed and there is a chance of loss of privacy and confidentiality affecting your reputation.
- **BENEFITS:** There are no direct benefits to you if you agree to be in this research study. However, your teen may learn some ways to help cope with stressful thoughts.
- **ALTERNATIVES TO PARTICIPATION:** Your decision to participate in this study will not affect your teen’s case or any court proceedings. If you don’t want to participate in this study, your teen can receive any care your worker decides is useful.

1. Researcher(s):

This research is being conducted by Anthony Spirito, PhD at Brown University, and Kathleen Kemp, PhD at Miriam Hospital. Dr. Spirito may be contacted at anthony_spirito@brown.edu or 401-444-1929. Dr. Kemp may be contacted at Kathleen_kemp@brown.edu or 401-793-8269.

2. What is this study about?

We are trying to figure out new ways to better help court-involved teenagers who report having hard to control emotions/impulses and/or thoughts of hurting themselves.

3. What will I be asked to do?

Today, you will complete a form about your demographics, obstacles to getting counseling for your teen, services you have received, satisfaction with those services, your family, and your and your teen’s mood and behavior. Your teen will be asked to complete a questionnaire about their demographics, thoughts of wanting to hurt themselves as well as traumatic/violent experiences, general feelings/behaviors, thoughts about getting counseling help, thoughts on their peers and other relationships, and substance use. You will answer questions regarding obstacles to getting you to counseling, services you have received, satisfaction with those services, your family, and your and their mood and behavior.

After completing the questionnaires, you and your teen will then be randomly assigned – by something like a flip of a coin - to either: 1) have your teen speak with a counselor about the results from the questionnaires you complete today and hard to control feelings/impulses and/or thoughts of wanting to hurt yourself today. The counselor will call you in one week to check in on you; or 2) have your teen speak with a counselor about the results from the questionnaires you complete today and receive education/handouts about things that trigger emotional outbursts and/or thoughts hurting yourself. Your teen may also be referred to talk



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to someone about your thoughts and feelings. In both cases, the session with the counselor will be audio recorded. The assessment and counseling session (whether it is today or in 3 months' time) will take 60-90 minutes in total. This session can happen in person, via phone, an emailed link, or via a zoom video conferencing call.

In 1 and 3 months from now, you and your teen will be asked to complete some of the questionnaires you completed today, again. The one-month appointment should take about 20 minutes of your time, the 3 month appointment should take 60-90 minutes. If you are chosen for the second group, your teen will also have option meet with a counselor for 30 minutes to discuss hard to control emotions/impulses and/or any thoughts he/she may have of wanting to hurt themselves. These sessions can happen in person, via phone, an emailed link, or via a zoom video conferencing call.

We will also collect information from your teen's court file, including: information about involvement with the Rhode Island Family Court, such as number of charges, types of past charges, and whether your teen receives any new charges during the course of the study. We will also collect any information on mental health screening at the Rhode Island Family Court and previous mental health treatment referrals if this information is in your court record.

If your teen were to become detained or incarcerated at the Rhode Island Training School or another detention or correctional facility over the course of the study, their participation would be forfeited for the follow-up appointments that overlap with their incarceration.

4. Will I be paid?

You and your teen will each receive \$30 for answering the questionnaires today. In 1 month time, you and your teen will each receive \$20 for completing the second session. In 3 months' time, you each will receive \$40 for completing the third session. If you complete all of these interviews, you each will receive \$90 in total. If you leave the study early or if we have to take you out of the study you will only be given compensation for the visits you've completed. If the session is completed via phone, zoom video call, or email, payment will be mailed following completion of the session.



TABLE 1.	All parents	All teens
Baseline Assessment [\$30]	<u>Parent assessment</u> (about 45 minutes) <ul style="list-style-type: none"> • Demographics • Parent questionnaires on barriers to receiving counseling, services you've received, satisfaction with those services, your family, your and your teen's mood and behavior • Persons to contact if we cannot reach you (optional) 	<u>Teenager assessment</u> (about 45 minutes) <ul style="list-style-type: none"> • Demographics • Adolescent questionnaire on thoughts about hurting self, traumatic/violent experiences, and other feelings/behaviors • Adolescent questionnaires on substance use • Adolescent questionnaires on peer and family relationships • Adolescent questionnaires on motivation for receiving treatment
Counseling session	Parents and Teens will be randomly selected to either: <ol style="list-style-type: none"> 1. Meet with a mental health counselor (30 minutes receive education about things that trigger emotional outbursts and/or thoughts hurting yourself This session will be audio recorded. or 2. Meet with a mental health counselor (30 minutes) receive education/handouts about things that trigger emotional outbursts and/or thoughts hurting yourself. This session will be audio recorded. 	
1-Month Assessment [\$20]	<u>Parent assessment</u> (about 20 minutes): <ul style="list-style-type: none"> • Parent questionnaires on barriers to teen treatment, teen's motivation for treatment, and family relationships. • Feedback questionnaire on intervention and counseling 	<u>Teenager assessment</u> (about 20 minutes): <ul style="list-style-type: none"> • Adolescent questionnaires on thoughts about hurting oneself, traumatic/violent experiences, and other feelings/behaviors. • Questionnaires on peer and family relationships, and motivation for treatment • Feedback questionnaire on intervention and counseling.
3 Month Assessment [\$40]	Parents and teens complete questionnaires about what services they received in the community and how satisfied they were with those services, and family dynamics (about 20 minutes). Parents complete a questionnaire about obstacles to receiving treatment, as well as teen and self-report behavioral symptoms (about 15 minutes); teens complete questionnaires about thoughts of hurting oneself, traumatic/violent experiences, general feelings/behaviors, and substance use (20 minutes). <p>[If group 2:] You have the option to have your teen meet with a mental health counselor (30 minutes) to discuss hard to control feelings/impulses and/or thoughts of wanting to hurt yourself today.</p>	



5. What are the risks?

The interview and questionnaires that we use in this study have been completed by other teenagers who have been involved in the courts. The questionnaires you will be answering will ask your own mental health and personal experiences which may cause you some discomfort. You can refuse to answer any questions you do not like. You can also stop your participation in the study at any time. There is a risk of loss of privacy in this study including sensitive information on your or your teen's emotional state and your teen's substance use. The information you and your teen share with us could affect your and their reputation and employability and could lead to negative legal consequences if it were disclosed with people outside of the study. Please refer to the section entitled "How will our information be protected?" for further information on the risk of loss of privacy.

If your teen consents to participate, we will be asking your teen about their general feelings and behaviors, suicidal thoughts and behaviors, traumatic/violent experiences, and substance use. Some of these questions may make your teen feel uncomfortable or bring up unpleasant feelings or memories. Your teen can refuse to answer any questions they do not like. Your teen can also stop their participation in the study at any time.

6. What are the benefits?

[There may be no benefits to participating in this study. There is a possibility that participating in this research study may positively affect your relationship with Rhode Island Family Court by satisfying the Probation Officer's concerns that your teen should receive further mental health evaluation. However, this cannot be guaranteed and the same positive effect may occur by arranging for further mental health evaluation outside of being in this study.]

7. How will my information be protected?

All of your and your teen's records from this study will be treated as private records. The records will be protected according to the rules of Brown University. Your and your teen's names will not be on the questionnaires. Records will be kept in a locked filing cabinet in a locked office at Brown University. Only researchers working on this study will have access to the information provided by you.

All laptop computer data as well as any paper data that is entered into a computer database will be accessible only to research staff members and will be password protected. All paper data will be stored in locked file cabinets behind locked doors and will only be accessible to research staff members. Only research staff who have direct contact with you and your teen will have access to your identity.

In this study we will be audio recording the counseling sessions with your teen who will provide separate consent for their participation. We will use a digital recorder. We will keep this information confidential. We will keep the information we collect about your teen,



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including audio recordings, during the research for study record keeping. Your teen's name and other information that can directly identify you will be stored securely and separately from the research information we collected from you. At the end of the study, audio tapes will be destroyed. We may use or share your teen's research information for future research studies (excluding audio tapes), but it will be deidentified, which means it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional consent for these studies. We may also share your and your teen's deidentified information with other researchers here, or at other institutions in the United States or around the world.

Brown University and Lifespan/Miriam Hospital staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

We will not disclose details regarding your answers to your teen or the court. However, your teen's Probation Officer or worker will know you are in the study. Also, if your teen reports they are actively suicidal, or plan to hurt someone else, we will get your teen help by telling appropriate authorities and taking appropriate medical action. In a situation that we are worried about your teen's safety, the research team may have to tell someone that you were a research participant in this study.

To help us protect your privacy, we have obtained a certificate of confidentiality from the National Institutes of Health (NIH). The researchers can use the Certificate to legally 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. The information you share with us can still be requested by the National Institute of Health for the purposes of auditing. You 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. The Certificate of Confidentiality will not be used to prevent disclosure to the state or local authorities of such as child abuse and neglect, or harm to self or others.

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 website at any time.

8. Are there any alternatives to this study?

If you don't want to participate in this study, your teen can receive any care their Probation



Officer or worker decides is useful. Your teen can also separately consent to their participation in the study.

9. What if I want to stop?

You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time. Your decision to participate in this study will not affect your teen's case or any court proceedings.

If you refuse to participate in or leave the study, your teen's current or future relationship with Brown University or Lifespan will not be affected.

10. Who can I talk to if I have questions about this study?

If you have any questions about this study, you can contact Dr. Anthony Spirito at (401) 444-1929 or Anthony_Spirito@Brown.edu.

11. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu. If English is not your first language the HRPP will find someone who is able to speak with you.

12. National Institute of Mental Health Data Archive (NDA)

Data from this study, including information about you, may be submitted to the NDA, a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code. With an easier way to share, researchers hope to learn new and important things about mental illnesses.

During and after the study, the researchers will send deidentified information about your teen's health and behavior to NDA. Other researchers nationwide can then apply to the NIMH to obtain access to your deidentified study data for research purposes.

Although only your teen's deidentified data will be shared with other researchers requesting access through the NDA, specific identifying information is required by the NDA in order to assign a Global Unique Identifier (GUID) to you. This information includes your teen's full name, biological sex, date of birth, and city/state of birth. We will collect this information from your teen by having your teen complete an NDA Information Form, if your teen agrees to share their data with the NDA. This information will be submitted to the NIMH via the NDA, and your teen will have a GUID assigned to you and linked only to your teen's identity. NIMH



is the only entity that will have access to your teen’s identifying information, which will be stored in the NDA GUID database. Once your teen has a GUID within the NDA system, any data collected from your teen in future studies that use the NDA can be linked to the data that we share from this study.

Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to privacy, and they will not share your teen’s identity. The NDA also has a Certificate of Confidentiality to protect your teen’s privacy, and that document will not waive any of the protections of the Certificate of Confidentiality granted for this study.

You and your teen may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about data you contributed to NDA.

Your teen may decide now or later that they do not want to share their information using NDA. If your teen decides in the future that they do not want their information included in the NDA, your teen can contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. NDA information is available on-line at <https://data-archive.nimh.nih.gov>.

Please initial below if you would like to be contacted by our research team for future studies should you/your teen be eligible. This will allow us to contact you if other research opportunities become available, and you can make a decision at that time if you would like to participate.

_____ I would like to be contacted for future research studies

13. Consent to Participate

Your signature below or verbal consent shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

_____ Verbal consent [Audio recording of consent may be found on Stronghold – DPHB: Safety]



BROWN

Participant's Signature and Date

/

PRINTED NAME

Research Staff Signature and Date

/

PRINTED NAME