



Combined Consent Documents for: Coping and Emotional Development for Adolescents to Reduce Stress for Adolescents (CEDARS) Intervention Study

Attached: Adolescent Assent, Adult Consent, Parental
Permission

NCT: NCT04958694

Date: Nov. 2, 2023



Adolescent Agreement to Take Part in a Research Study

Study Name: CEDARS: Intervention (IRB 2021-4642)

Name of Study Doctor/Researchers: Nia Heard-Garris, MD, MSc

We want to tell you about a research study for which you might qualify being conducted by a researcher at Ann & Robert H. Lurie Children's Hospital of Chicago ("Lurie Children's"). Research studies help us learn more about experiences and develop new ways to help. Taking part in a research study is voluntary. It is your choice to take part in this research study. You may talk to others, such as your family or other trusted adults before you decide to take part in this study. The study staff will also explain the study to you and answer any questions that you may have.

Why is this study being done?

Positive affect interventions are designed to improve coping in individuals with chronic or ongoing stress and can be tailored to target health behaviors. The purpose of this study is to pilot a previously designed stress-reduction intervention, using a positive affect approach. Our goal is to provide adolescents with tools to cope with stressful situations and manage their stress.

We have created an online video platform called CEDARs which consists of 7 videos that teach basic coping skills which have been shown to improve positive emotions. We plan on having one group of twenty teens watch one video per week and try to implement the skills that they learn in their daily lives. These teens will also complete mental health measures at week 1, week 4, week 8, and one-month post study completion, so the researchers can determine if completing the intervention improved their mental health outcomes. Teens will also be asked for general feedback about the length and content of the video.

We will also have another group of teens who will only complete the mental health measures at week 1, week 4, week 8-, and one-month post intervention. They will be compared to the teens completing the online intervention to see if there are any differences in their mental health outcomes. However, this group of teens will also receive access to the videos one month after the study completion to ensure they have access to the same resources as their peers.

Teens will be assigned to either the treatment group or control group based on their demographics and experiences, to ensure that both groups are similar in structure.

What will happen in this study?

If you agree to be in this study and you are assigned to the treatment group, you will take part in a seven-week to eight, virtual stress reduction intervention. Each week you'll complete one video and answer some feedback questions about the video you watched. During week 1, week 4, and week 8 of the study you will also complete mental health surveys to see if your mental health improved as a result of learning these new skills



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Note: Label required for cover page, but is optional for other pages if the following information is provided:

Patient Name:

MRN:

If you agree to participate in the study and are assigned to the control group you will only complete the mental health measures that are a part of this study. This means you will complete mental health surveys at week 1, week 4, week 8, and 1 month after the study completion.. However, we will give you access to all of the videos one month after the end of the study.

What are the bad or harmful things that could happen in this study?

Risks related to breach of confidentiality

Every research study involves some risk to your private information. It is possible that other people could find out you were in the study or see your study information. However, we will take every step possible to keep your information private and secure.

Risks related to intervention sessions

The questions asked during the sessions might include sensitive topics. If you are uncomfortable with any subjects, you do not have to participate. If any of the discussions cause you concern, please alert the study staff or a trusted adult.

What are the good things that could happen in this study?

You might benefit from taking part in the interventions by learning and putting into practice new tools to reduce and manage your stress.

What other options are there?

You are not obligated to participate in research. If you join the study and then change your mind, it is okay for you to leave this study.

Who will see your information?

The study team may share your information and samples for future research. They will remove identifying information, such as your name and other information that can be linked to you before this is done. The study team and other researchers may use this for other studies without getting consent from you.

Will there be payment or gifts for being in this study?

You will be compensated \$25 per mental health assessment completed. There are four mental health surveys associated with this study. They will be completed at week 1, week 4, week 8, and one month after the study has completed. Your child will receive \$100 in total compensation if they complete all the mental health measures in the study.

Who can answer questions about this study?

You can ask Dr. Nia Heard-Garris or her research staff anything about the study.

You can ask Dr. Heard-Garris anything about the study. If you are not happy with this study and want to talk with someone else, not the study doctor or the people working with the study doctor, you may contact the IRB Office by telephone at (312) 503-7110 or by email at IRB@luriechildrens.org.



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You will be given or emailed a copy of this consent form.

May we contact you for future health studies via phone or email?

Please **select** to your choice below:

	YES – I agree to be contacted for future health studies via phone or email.
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	NO – I do not agree to be contacted for future health studies via phone or email.
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Signatures

Participant Assent:

By selecting “I agree”, I affirm:

- 1) I have read this form.
- 2) The research has been explained to me.
- 3) All of my questions have been answered. I give my assent to take part in this research study.

I agree	Date:
I do not agree	

Signature of Authorized Person Obtaining Assent:

I certify that I have explained the above to the participant/LAR and the signature was obtained voluntarily.

Signature:

Printed Name:

When it is not possible to obtain written assent:

To be completed by the Person Obtaining Assent.

	This adolescent is unable to given written assent, but has given verbal assent to participate in the study.
Initials	

	This adolescent is unable to give written or verbal assent. The study PI (or delegate) has
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Initials	obtained a waiver of assent from the IRB Chair. Note: To request a waiver, e-mail IRB@LurieChildrens.org .
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Adult Consent to Take Part in a Research Study

Name of Study: CEDARS: Intervention IRB 2021-4642

Name of Researcher (referred to as the study doctor): Dr. Nia Heard-Garris

We want to tell you about a research study for which you might qualify being conducted by a researcher at Ann & Robert H. Lurie Children's Hospital of Chicago ("Lurie Children's"). Research studies help us learn more about experiences and develop new ways to help. Taking part in a research study is voluntary. It is your choice to take part in this research study. You may talk to others, such as your family or other trusted adults before you decide to take part in this study. The study staff will also explain the study to you and answer any questions that you may have.

What are the purpose and goals of this study?

Positive affect interventions are designed to improve coping in individuals with chronic or ongoing stress and can be tailored to target health behaviors. The purpose of this study is to pilot a previously designed stress-reduction intervention, using a positive affect approach. Our goal is to provide adolescents with tools to cope with stressful situations and manage their stress.

We have created an online video platform called CEDARs which consists of 7 videos that teach basic coping skills which have been shown to improve positive emotions. We plan on having one group of twenty teens watch one video per week and try to implement the skills that they learn in their daily lives. These teens will also complete mental health measures at week 1, week 4, week 8, and one-month post study completion, so the researchers can determine if completing the intervention improved their mental health outcomes. Teens will also be asked for general feedback about the length and content of the video.

We will also have another group of teens who will only complete the mental health measures at week 1, week 4, week 8-, and one-month post intervention. They will be compared to the teens completing the online intervention to see if there are any differences in their mental health outcomes. However, this group of teens will also receive access to the videos one month after the study completion to ensure they have access to the same resources as their peers.

Teens will be assigned to either the treatment group or control group based on their demographics and experiences, to ensure that both groups are similar in structure.

If I agree to take part in this study, what would I need to do?

If you agree to be in this study and you are assigned to the treatment group, you will take part in a seven-week to eight, virtual stress reduction intervention. Each week you'll complete one video and answer some feedback questions about the video you watched. During week 1, week 4, and week 8 of the study you will also complete mental health surveys to see if your mental health improved as a result of learning these new skills



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If you agree to participate in the study and are assigned to the control group you will only complete the mental health measures that are a part of this study. This means you will complete mental health surveys at week 1, week 4, week 8, and 1 month after the study completion.. However, we will give you access to all of the videos one month after the end of the study.

What are the bad or harmful things that could happen in this study?

Risks related to breach of confidentiality

Every research study involves some risk to your private information. It is possible that other people could find out you were in the study or see your study information. However, we will take every step possible to keep your information private and secure.

Risks related to intervention sessions

The questions asked during the sessions might include sensitive topics. If you are uncomfortable with any subjects, you do not have to participate. If any of the discussions cause you concern, please alert the study staff or a trusted adult.

What are the benefits from this study?

You might benefit from taking part in the interventions by learning and putting into practice new tools to reduce and manage your stress.

What other options do I have?

You are not obligated to participate in research. If you join the study and then change your mind, it is okay for you to leave this study.

Will your information be used in future studies?

The study team may use your information for future research. They will remove identifying information, such as your name and other information that can be linked to you before this is done. The study team and other researchers may use this for other studies without getting consent from you.

The contact information you provide during the study will be stored securely and will not be shared. This information might be used to contact you about future studies.

Will there be payment or gifts for being in this study?

Your child will be compensated \$25 per mental health assessment completed. There are four mental health surveys associated with this study. They will be completed at week 1, week 4, week 8, and one month after the study has completed. Your child will receive \$100 in total compensation if they complete all the mental health measures in the study.

Who can answer questions about this study?

You can ask your study doctor, nurse or other people working with them on the study Dr. Nia Heard-Garris at achip@luriechildrens.org.



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MRN:

You can ask Dr. Heard-Garris anything about the study. If you are not happy with this study and want to talk with someone else, not the study doctor or the people working with the study doctor, you may contact the IRB Office by telephone at (312) 503-7110 or by email at IRB@luriechildrens.org.

We will tell you if we learn new information that may make you change your mind about being in this study.

Signatures:

Participant Signature:

By signing this form, I affirm:

1. I have read this form.
2. The research has been explained to me.
3. All of my questions have been answered.
4. I give my consent to take part in this research study.

Signature of Participant or Legally Authorized Representative (LAR):

Date:

Printed Full Name:

Signature of Authorized Person Obtaining Consent/Witness*:

I certify that I have explained the above to the participant/LAR and the signature was obtained voluntarily.

Signature:

Date:

Printed Full Name:

**If the study includes the use of records related to mental health or developmental disabilities, the person obtaining consent also serves as the witness to consent for use of relevant records.*

Signature of Interpreter/Witness*:

☐

Not applicable, no interpreter used.

I attest that the study information has been presented to the participant/ LAR in their native language.

Signature of Interpreter/Witness:

Printed Full Name or Unique Phone ID/Company Name:



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MRN:

Note to Investigators: When obtaining consent from a non-English speaking participant/LAR

When a study-specific translated consent document is not available, a translated “short form” (available in several languages on the IRB website) may be used, in combination with a verbal presentation of study information (as outlined in this English consent) with the aid of an interpreter.

- a. *The consent process must be witnessed by an individual who is fluent in both English and the language understandable the subject. The interpreter may serve as the witness and should sign both the English consent document and short form.*
- b. *The participant/LAR should sign the short form (in the language they understand).*
- c. *The investigator and/or study staff authorized by the IRB to obtain consent must sign the approved English version of the consent form.*
- d. *A copy of both the IRB-approved English consent form (i.e., the summary) and the translated version of the short form must be given to the participant/LAR.*

**Affix Patient Label Here**

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Patient Name:**MRN:**

Parent Permission for a Child to Take Part in a Research Study

Study Name: Cedars: Intervention(IRB 2021-4642)**Name of Researchers:** Nia Heard-Garris, MD, MSc

This consent form describes a research study for which your child might qualify being conducted by a researcher at Ann & Robert H. Lurie Children's Hospital of Chicago ("Lurie Children's"). Research studies help us learn more about conditions and develop new treatments. Taking part in a research study is voluntary. It is your choice to allow your child to take part in this research study. Please read this consent form and ask questions about anything you do not understand. You may talk to others such as your family or healthcare providers before you decide to allow your child to take part in this study. The study staff will also explain the study to you and answer any questions that you may have. Your decision will not affect your child's regular care.

What are the purpose and goals of this study?

Positive affect interventions are designed to improve coping in individuals with chronic or ongoing stress and can be tailored to target health behaviors. The purpose of this study is to pilot a previously designed stress-reduction intervention, using a positive affect approach. Our goal is to provide adolescents with tools to cope with stressful situations and manage their stress.

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We will also have another group of teens who will only complete the mental health measures at week 1, week 4, week 8-, and one-month post intervention. They will be compared to the teens completing the online intervention to see if there are any differences in their mental health outcomes. However, this group of teens will also receive access to the videos one month after the study completion to ensure they have access to the same resources as their peers.

Teens will be assigned to either the treatment group or control group based on their demographics and experiences, to ensure that both groups are similar in structure.

If I agree to have my child take part in this study, what would my child need to do?

If you agree for your child to be in this study, they will take part in a seven to nine week, virtual stress reduction intervention. Each week they will complete an online video and questionnaire designed to teach tools for stress management and coping, for a total of seven sessions each lasting 30-50 minutes at a time.



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They will also take part in multiple follow-up sessions throughout the program to help access the feasibility of the online intervention. The first one will take place likely after the second session, and subsequent check-ins to follow.

What are the risks, side effects, or discomforts related to the study?

Risks related to breach of confidentiality

Every research study involves some risk to your private information. It is possible that other people could find out you were in the study or see your study information. However, we will take every step possible to keep your information private and secure.

Risks related to intervention sessions

The questions asked during the sessions might include sensitive topics. If your child is uncomfortable with any subjects, they do not have to participate. If any of the discussions cause your child concern, they will be encouraged to alert the study staff or a trusted adult.

What are the benefits from this study?

Your child might benefit from taking part in the interventions by learning and putting into practice new tools to reduce and manage their stress.

What other options does my child have?

You may decide to not to allow your child to participate in the study. You may also decide to have your child stop participating at any time. Your child will receive the same care from your doctor regardless of your decision to participate in the study.

What if the researcher or I do not think my child should stay in the study?

Your child can stop taking part in this study at any time. If they join the study and change their mind, they can leave the study without any repercussions.

Important New Information:

We will tell you if we learn new information that may make you change your mind about your child being in this study.

Will my child's information be used in future research studies?

The study team may use your child's information for future research. They will remove identifying information, such as their name and other information that can be linked to them before this is done. The study team and other researchers may use this for other studies without getting consent from you.

The contact information you provide during the study will be stored securely and will not be shared. This information might be used to contact you about future studies.

Costs Related to this Study:



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There are no study related costs to you or your insurance company.

Payment for Taking Part in this Study:

Your child will be compensated \$25 per mental health assessment completed. There are four mental health surveys associated with this study. They will be completed at week 1, week 4, week 8, and one month after the study has completed. Your child will receive \$100 in total compensation if they complete all the mental health measures in the study.

Who can answer my questions about this study?

If you have any questions, contact the principal investigator, Dr. Nia Heard-Garris at achip@luriechildrens.org.

If you have questions about your rights or if you have a complaint, you can call the IRB Office at (312) 503-7110; or via email at IRB@luriechildrens.org.

Additional Information:

Printed Name of Child:

Parent/LAR Signature:

By signing this form, I affirm:

1. I have read this form.
2. The research has been explained to me.
3. All of my questions have been answered. I give my consent for my child to take part in this research study.

Signature of Parent or Legally Authorized Representative (LAR):

Date:

Printed Full Name:

Relationship to Child:

Signature of Authorized Person Obtaining Consent witness*:

I certify that I have explained the above to the parent(s)/LAR and the signature(s) was obtained voluntarily.

Signature:

Date:

Printed Full Name:



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Patient Name:

MRN:

**If the study includes the use of records related to mental health or developmental disabilities, the person obtaining consent also serves as the witness to consent for use of relevant records.*

Signature of Interpreter/Witness*:

☐	Not applicable, no interpreter used.
I attest that the study information has been presented to the parent/LAR in their native language.	
Signature of Interpreter/Witness:	
Printed Full Name or Unique Phone ID/Company Name:	

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- b. *The parent/LAR should sign the short form (in the language they understand).*
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