

## Cover page

**Principal Investigator:** Alison Salloum, PhD., LCSW

**Study Title:** Stepped Care for Children after Trauma: Optimizing Treatment

**Document title:** Informed consent form for child age 12

**Document date:** 12/7/2019

**USF IRB number:** Pro00022129

**NCT number:** NCT02537678





## **Assent of Children to Participate in Research (age 12)**

**Pro # 00022129**

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### **Title of study: Stepped Care for Children after Trauma: Optimizing Treatment**

#### **Why am I being asked to take part in this research?**

You are being asked to take part in a research study about how to help children after something traumatic happens. You are being asked to take part in this research study because you have had something bad or scary happen. If you take part in this study, you will be one of about 246 children participating. Parents and counselors will also participate in the study

#### **Who is doing this study?**

The person in charge of this study is Dr. Alison Salloum. However, other research staff may be involved and can act on behalf of the person in charge.

#### **What is the purpose of this study?**

We hope to learn helpful ways to help children who are having a lot of stress due to something really bad, scary or terrible that has happened.

#### **Where is the study going to take place and how long will it last?**

The study will be take place at the Crisis Center of Tampa Bay, Directions for Living, Children's Home Society or USF St. Petersburg Family Study Center. You will be asked to participate in five assessments which will take anywhere from 1 to 3 hours. You will also be asked to complete assessments during counseling and participate in counseling. The total amount of time you will be asked to volunteer for this study is approximately 22 hours over the next year.

#### **What will you be asked to do?**

Here is what we will ask you to do:

**Assessments.** We would like to ask you a lot of questions about your thoughts and feelings and about the scary or bad thing that happened. We will ask you all of these questions to see if you are having a lot of stress and are feeling sad.

If you are having a lot of stress, you may be able to participate in a counseling project. After we meet with you and your parent or guardian, we will talk with you and your parent or guardian more about the project to see if you will be participating or not.



If you will not be participating more in the counseling project, we will talk with your parent or guardian to see if there are other places that may be helpful.

If you are having a lot of stress and will be participating in the counseling project, you and your parent/guardian will be coming here to see a counselor because of the bad or scary thing that happened.

Three times during your counseling sessions you will be asked some questions about what you think about counseling and your counselor. You will answer these questions using a program called Qualtrics. If the program, you will have the option of filling it out on paper.

**Counseling.** You will randomly be placed in either Stepped Care Trauma-Focused Cognitive Behavioral Therapy (SC-TF-CBT) or standard Trauma-Focused Cognitive Behavioral Therapy (TF-CBT). There is a 50/50 chance of being assigned to one or the other type of counseling.

If you are in Stepped Care TF-CBT, we will ask you to work with your parent or guardian to complete the My Steps book. You and your parent or guardian will have special parent-child meetings where you will work on the activities in your book. You will be taught ways to relax, ways to tell your feelings, and ways to calm down. You will be asked to talk about the scary thing that happened and you will learn to make it not so scary anymore. You will be working on making the scary feelings go away. Once you finish your book we will see if you have a lot of stress or not. If you do not have a lot of stress and you are feeling better about what happened, you will be finished with the counseling. If you are having a lot of stress and are not feeling better about what happened, you will be asked to meet 9 more times with the therapist.

**Assessments.** You will also be asked to complete surveys every time you either meet with your parent to complete My Steps or when you meet with the therapist. The questions are about changes in your thinking that may have occurred due to the trauma, and how scared or upset you feel. Three times at the office we will take your heart rate and do a test called a skin conductance test which involves placing a wristband on your wrist. You will first watch a common child-friendly movie for 5 minutes and then we will ask you questions about the trauma for 5 minutes. During the questions, we will be able to measure how keyed up your body is when talking about the trauma.

**Summary.** If you participate, here is a list of everything you will be asked to do:

1. Complete five main assessments at the beginning, middle and end of counseling and then at 6 and 12 after counseling is over.
2. Participate in either Stepped Care TF-CBT or standard TF-CBT.
3. Fill out surveys during counseling.
4. Participate in three heart rate and skin conductance tests where we measure your body's response.

## **What things might happen if you participate?**

As far as we know, the things you will be doing will not harm you or make you have any more upsetting feelings. Although we have tried to make sure that you do not get too upset, you may find some activities make you feel upset, and you may even experience feeling a little worse for a small time. If you get too upset, we do not think it will last long. We will help you by stopping the assessment for a



minute or longer until you feel okay, or if you are receiving counseling you may be provided with some more sessions. We will teach you ways to calm yourself down. We will also teach you to let us and your parent or guardian know when you are feeling really scared or upset. Again, we do not know of any way that this study can harm you.

### **Is there benefit to me for participating?**

We cannot promise that you will feel better from taking part in this research. However, most children have experienced less stress, less anger, and not have so many sad, angry or scared feelings after talking about the scary thing that happened. We cannot promise that you will receive benefit from taking part in this research study.

### **What other choices do I have if I do not participate?**

You do not have to participate in this research study. Your parent or guardian can talk with other counselors at the agency (Crisis Center of Tampa Bay, Directions for Living, Children's Home Society, and USF St. Petersburg Family Study Center) about receiving regular therapy services.

### **Do I have to take part in this study?**

You should talk with your parents or guardian and others about taking part in this research study. If you do not want to take part in the study, that is your decision. You should take part in this study because you want to volunteer.

### **Will I receive any compensation for taking part in this study?**

You will be provided a small toy, crayons, pencils, stickers, bouncy balls or something like these things twice during treatment: sessions 2 and 3 for Stepped Care TF-CBT or sessions 5 and 8 for standard TF-CBT for participating in the assessments, and after each heart rate and skin conductance test.

### **Who will see the information about me?**

Your information will be added to the information from other people taking part in the study so no one will know who you are. However, we may share the information with your parent or guardian and counselor so that can help you better. Also, by law, there are some times, such as child abuse, neglect, feeling like killing yourself or others, where we may need to let the appropriate authorities know.

### **Can I change my mind and quit?**

If you decide to take part in the study you still have the right to change your mind later. No one will think badly of you if you decide to stop participating. Also, the people who are running this study may need for you to stop. If this happens, they will tell you when to stop and why.

### **What if I have questions?**

You can ask questions about this study at any time. You can talk with your parents, guardian or other adults about this study. You can talk with the person who is asking you to volunteer by calling Dr. Alison



Salloum at 813-974-1535. If you think of other questions later, you can ask them. If you have questions about your rights as a research participant you can also call the USF IRB at (813) 974-5638.

### **Assent to Participate**

I understand what the person conducting this study is asking me to do. I have thought about this and agree to take part in this study. I have been given a copy of this form.

\_\_\_\_\_  
Name of person agreeing to take part in the study

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name & signature of person providing information (assent) to subject

\_\_\_\_\_  
Date



**Cover page**

**Principal Investigator:** Alison Salloum, PhD., LCSW

**Study Title:** Stepped Care for Children after Trauma: Optimizing Treatment

**Document title:** Informed assent for children age 7 to 11

**Document date:** 12/7/2019

**USF IRB number:** Pro 00022129

**NCT number:** NCT02537678





## **Verbal Script for Children ages 7 to 11 Stepped Care for Children after Trauma: Optimizing Treatment**

### **IRB Study # Pro00022129**

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We are doing this research study because we hope to learn helpful ways to help children who are having a lot of stress due to something really bad, scary or terrible that has happened. The person in charge of this study is Dr. Alison Salloum. The study is called Stepped Care for Children after Trauma: Optimizing Treatment

We would like to ask you a lot of questions your thoughts and feelings and about the scary or bad thing that happened. We will ask you all of these questions to see if you are having a lot of stress and are feeling sad.

If you are having a lot of stress, you may be able to participate in a counseling project. After we meet with you and your parent, we will talk with you and your parent/caregiver more about the project to see if you will be participating or not.

If you will not be participating more in the counseling project, we will talk with your parent/caregiver to see if there are other places that may be helpful. If you are having a lot of stress and will be participating in the counseling project, you and your (insert name that child calls the caregiver, such as mom) will be coming here to see a counselor because of the bad or scary thing that happened. Some children will work in a special workbook at home with their parent/caregiver and meet with the counselor three or more times and other children will meet with the counselor here at the center every week for 12 to 24 times or about 3 months.

If you take part in this study, you will be asked to:

1. Complete 5 main assessments at the beginning, middle and end of counseling and then at 6 and 12 months later. For these, assessments we will ask you a lot of questions about how you have been thinking, feeling and behaving.
2. Participate in either Stepped Care TF-CBT or standard TF-CBT. Stepped Care involves first working with your parent or guardian at home in a workbook called My Steps and meeting with the therapist three times. That may be enough counseling for you, or you may need to “step up” and see a therapist for about 9 more times. Standard TF-CBT will involve seeing a therapist every week for 12 times and sometimes having your parent or guardian meet with you and the therapist.
3. Fill out surveys during counseling. 12 times you will be asked to fill out a survey about how you have been thinking since the trauma and how scared or upset you feel. Three times during your counseling sessions you will be asked some questions about what you think about counseling and your counselor.



You will answer these questions using a program called Qualtrics. If the program, you will have the option of filling it out on paper.

4. Participate in three heart rate and skin conductance test where we measure your body's response. Three times at the office we will take your heart rate and do a test called a skin conductance test which involves placing a wristband on your wrist. You will first watch a common child-friendly movie for 5 minutes and then we will ask you questions about the trauma for 5 minutes. During the questions, we will be able to measure how keyed up your body is when talking about the trauma.

You will be provided a small toy, crayons, pencils, stickers, bouncy balls or something like these things twice during treatment: sessions 2 and 3 for Stepped Care TF-CBT or sessions 5 and 8 for standard TF-CBT for completing the assessments, and after each heart rate and skin conductance test.

We are trying to learn about ways to help children who have had bad, scary or terrible things happen. Do you have any questions about this?

**Assent to Participate**

Ask the child: Do you understand what we are asking you to do? Do you have any more questions about the research study? (Wait and allow the child to think.)

Ask the child "Do you want to be in this study or not?"

Record child's assent to be in the study: Circle Yes or No

Name of child agreeing to take part in the study:

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Name of person who reviewed the verbal assent with the child:

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Name

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Date

