Cover page

Principal Investigator: Alison Salloum, PhD., LCSW
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UNIVERSITY OF SOUTH FLORIDA

Consent to Participate in Research & Parental Permission for my Child to Participate in Research

Pro # 00022129

The following information is being presented to help you and your child decide whether or not you would like to be a part of a research study. Please read this information carefully. If you have any questions or if you do not understand the information, we encourage you to ask the researcher.

We are asking you to take part, and to allow your child to take part, in a research study called:
Stepped Care for Children after Trauma: Optimizing Treatment

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

The research will be conducted at the Crisis Center of Tampa Bay, Directions for Living, Children's Home Society or USF St. Petersburg Family Study Center.

This research is being sponsored by the National Institute of Mental Health (NIMH).

Purpose of the study:

The purpose of this research study is to develop and test a stepped care trauma-focused cognitive behavioral therapy (Stepped Care TF-CBT) program for children so that treatment is available for children after trauma. We also want to know if children's body reactions from trauma improve during treatment.

Why are you & your child being asked to take part?

We are asking your child to take part in this research study because you reported that your child has experienced a trauma. We want to learn different ways of treating children who have experienced a traumatic event(s).

Study Procedures:

Both the parent and child will be asked to participate in the study. The study is designed for one parent to take the lead on working with the child and the therapist, and this parent will be considered the lead parent.

If you take part in this study as the lead parent, you and your child will be asked to do the following:

First assessment: You will be asked to participate in an assessment. It will last about three hours. We will ask you questions about you and your child. We want to learn how distressed your child is about the traumatic event(s). This assessment will be used to see if your child qualifies for the study. It will also be used to see if any improvements happen if your child participates in stepped care.

Questions we will ask you will include questions about your depression, past trauma, mental health, and parenting stress.

Questions about your child will include questions about your child's past trauma, depression, and emotional and behavioral questions.

All parents are asked to take part in this assessment. Children ages 7 to 12 will be asked to complete more assessment information than children ages 4 to 6. The questions will be about how they have been thinking, feeling and behaving since the traumatic event(s).

Mid-treatment assessment: At the middle point of treatment, you and your child will be asked to take part in an assessment about progress of treatment, and the child's symptoms and functioning. This assessment should take about an hour.

Post-assessment: After treatment, you and your child will be asked to repeat all of the measures that were completed in the first assessment. This assessment will take approximately 2 hours.

6 and 12 months after-treatment: There will be two follow-up assessments, where you and your child will be asked to repeat all of the assessments that were completed during the post assessment. Each assessment will take approximately 2 hours.

If you are not the lead parent, you will be able to attend session 1 with your child and receive information. In some cases, both parents may be asked by the therapist to participate in additional therapy sessions. However, you will not need to attend any study visits.

Additional assessments:

Three times during treatment your child will be asked to participate in a ten minute test to see how much body reactions your child is experiencing due to the trauma. In others words, how keyed up your child's body is when talking about the trauma. This procedure is non-invasive. Your child's heart rate will be taken as well as what is called a skin conductance test which involves placing wristband on your child's wrist. The child will first watch a common child-friendly movie for 5 minutes and then we will ask your child structured questions about the trauma for 5 minutes. During the questions, we will be able to measure how keyed up their body is when taking about the trauma.

Every therapy session, you and your child will be asked to fill out brief measures about distress levels, fear, and changes in thinking due to the trauma. For parents who are not in the child's therapy sessions,

completing some of these measures may mean watching a brief video of the session and then completing the questions.

Assessments will be completed using various methods including in-office, at home, via phone, WebEx which allows online video and audio, email, mail, and Qualtrics, which allows assessment to be completed online. These options will be discussed with you with the USF research staff.

Therapy:

You and your child will be randomly assigned to either Stepped Care or standard Trauma-Focused Cognitive Behavioral Therapy (TF-CBT). Randomly assigned means you have a 50/50 chance of being assigned to one or the other counseling group.

If you receive Stepped Care TF-CBT, you will be asked to participate in Step One. In Step One, you and your child will meet with the therapist 3 times, read information for parents, access the internet to learn more about trauma and how to complete Step One, receive phone calls, and complete 11 parent-child meetings at home. After the mid-treatment assessment you and your child will either start the maintenance phase where you will keep doing everything you learned in Step One, or you may be asked to start Step Two, where you and your child will come to the office 9 times, once per week for standard TF-CBT counseling.

If you receive standard TF-CBT, you and your child will be asked to come to the office 12 times, once per week to meet with the therapist.

Participation in both Stepped Care TF-CBT and standard TF-CBT will last approximately 12 weeks.

The research will take place at the Crisis Center of Tampa Bay, Children's Home Society, Directions for Living, and USF St. Petersburg Family Study Center depending on which office is the closest to you.

Audio and video recording

All assessments will be audio-recorded and therapy sessions will be video-recorded and audio recorded. The purpose of this is to make sure that the assessments are being conducted as they are supposed to be and that the therapy we are providing is of good quality. These digital recordings will only be listened to by Dr. Salloum and her research staff.

When parents are not in the therapy session with the therapist and child, the parent will be asked to watch a specific part of the video recordings in order to complete some questions. In some cases, sessions may be audio and/or video-recorded. Sections of the recordings may be transcribed for data collection purposes. If the information is used from the audio or video-recordings for case examples of the treatment provided, no identifiable information about you and your child will be used. Pseudo names will be used. No identifying information will be reported. Dr. Salloum will keep the audio and video digital recording/files on her password protected computer that is locked in her office at USF, Tampa campus.

After data are collected from the taped therapy sessions, the tapes will be destroyed/deleted immediately. The assessment tapes will be retained for further research purposes for at least 5-years after the completion of the study. At that time, the tapes will be destroyed/deleted in a manner such that the tapes will not be audible. You and your child will not have access to the audio or video tapes. The tapes are for research purposes only.

Please check if you agree to be **audio-recorded** for the **assessments.**

❑ Yes, I agree to be audio-recorded for the assessments.

❑ No, I do not agree to be audio-recorded for the assessments.

Please check if you agree to be **video-recorded** for the **therapy sessions**.

❑ Yes, I agree to be video-recorded for the therapy sessions.

❑ No, I do not agree to be video-recorded for therapy sessions.

Please check if you agree to be **audio-recorded** for the **therapy sessions**.

❑ Yes, I agree to be audio-recorded for the therapy sessions.

❑ No, I do not agree to be audio-recorded for therapy sessions.

Total Number of Participants

Up to 510 individuals (children, parents, and therapists) will take part in this study.

Alternatives / Voluntary Participation / Withdrawal

If you decide not to let your child take part in this study and you do not participate, that is okay. Instead of being in this research study you and your child can choose not to participate.

You and your child should only take part in this study if both of you want to. You or your child should not feel that there is any pressure to take part in the study to please the study investigator or the research staff.

If you or your child decides not to take part you may talk with the agency (Crisis Center of Tampa Bay, Directions for Living, Children's Home Society or USF St. Petersburg Family Study Center) about receiving regular therapy services. You have the alternative to choose not to let your child participate in this research study.

You can decide after signing this informed consent form that you no longer want your child or yourself to take part in this study. We will keep you informed of any new developments which might affect your willingness to participate or allow your child to continue to participate in the study. However, you and your child can decide to stop taking part in the study for any reason at any time. If you and/or your child decide to stop taking part in the study, tell the study staff as soon as you can.

Benefits

The potential benefits to your child are that your child will learn about the effects of trauma (posttraumatic stress, which are stress reactions that occur after trauma exposure) and learn relaxation techniques. We do not know if your child will benefit by experiencing less posttraumatic stress, although that is anticipated.

Risks or Discomfort

There are no known risks to those who take part in this study. However, your child may experience mild discomfort resulting from the discussion of potentially difficult topics, such as about traumatic events. It is possible that some children may exhibit some regression when processing the trauma narrative, thus resulting in being temporarily worse.

In our experience most children welcome the opportunity to discuss their experiences with a trained clinician. If your child gets too upset, we will stop what we are doing until the stress goes down. We will teach your child ways to relax that will help your child learn to calm him or herself down. We will also teach them ways to let us and you know if they are feeling upset.

Compensation

You will be compensated $25 for the first assessment, $30 for the mid-assessment, $50 for post-treatment assessments and 6- and 12-month follow-up assessments ($205 total). If you and your child withdraw for any reason and do not complete the therapy you and your child may still complete the screening/baseline, mid-post, 6 and 12 month follow-up assessments and be compensated. You will also receive $10 for the additional assessment completed during therapy either at sessions 2 and 3 for Stepped Care TF-CBT or sessions 5 and 8 for standard TF-CBT (total $20.00). You may also be provided with bus passes to attend the assessments or in some cases, we may provide transportation services. You will be responsible for transportation to the therapy sessions.

Children will be provided a child-friendly small token of appreciation, such as a small toy, crayons, pencils, stickers, or bouncy balls 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. Water/juice and light snacks will be provided to children during the assessments.

Cost

You or your insurance company, Medicaid or a third party payer will be expected to pay the costs for the therapy sessions. The Crisis Center of Tampa Bay, Directions for Living, Children's Home Society or USF St. Petersburg Family Study Center will let you know what the cost is for the therapy, or you may wish to contact your insurance company to discuss this further.

You will not be responsible for the cost of the assessments. If you receive Stepped Care TF-CBT, you will not be responsible for the costs of the parent-child workbook and if your insurance does not cover the cost of the therapy phone calls, you will not be responsible for this cost of the therapist time on the therapy phone calls.

Conflict of Interest

The person leading this research study might benefit financially from this study. Specifically, Dr. Alison Salloum is one of the authors of the *Stepping Together* treatment manual. Research studies like the one you are thinking about joining are done to determine whether the new treatment is safe and effective. If research shows the new treatment is safe and effective, Dr. Salloum would receive a part of the profits from any sales of this treatment manual.

The Institutional Review Board that reviewed this study and a committee at the University of South Florida have reviewed the possibility of financial benefit. They believe that the possible financial benefit to the person leading the research is not likely to affect your safety and/or the scientific quality of the study. If you would like more information, please ask the researchers or the study coordinator.

Privacy and Confidentiality

The purpose of the assessments and therapy data are for research purposes only. You and your child will not have access to the research data including audio or video recordings, and the data collected <u>are not</u> for forensic or court purposes.

We will keep your child's study records confidential to the extent permitted by law. For example, if there is reasonable cause to suspect that a child is abused, neglected, or abandoned by a parent, legal custodian, caregiver, or other person responsible for the child's welfare, a report of such knowledge or suspicion will be made to the appropriate authorities.

If we learn information about you or your child that suggest intent to harm oneself (suicide) or other, we will share information with the Crisis Center of Tampa Bay, Directions for Living, Children's Home Society or USF St. Petersburg Family Study Center therapists or in cases of acute suicidality, with an emergency mental health service such as crisis assessment unit, or a hospital or make referrals for further evaluation to keep you and your child and others safe. We will also consult with other study team members. For children who are enrolled in the study, the therapist providing treatment will be made aware of any reported suicidal ideation so that the clinician can work with the child and family to provide appropriate intervention and monitoring. The parent will be informed of the child's suicidal ideation and will also be provided with appropriate resources should the child become suicidal such as taking the child to the hospital or to the community children's crisis center for an evaluation. If it is determined that the child may proceed in study treatment, the therapist will monitor the suicidal ideation by completing a harm to self or other form with the child, and in cases of young children (ages 4 to 6) the parent will be asked these questions about his or her child.

Certain people may need to see your study records. Anyone who looks at your records must keep them confidential. These individuals include:

- The research team, including the Principal Investigator, study coordinator, all other research staff, and the Data and Safety Monitoring Board who monitor the data and safety of the study.
- Certain government and university people who need to know more about the study, and individuals who provide oversight to ensure that we are doing the study in the right way.
- The USF Institutional Review Board (IRB) and related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance.
- The sponsors of this study (NIMH) and contract research organization. Please see the data sharing information below for sharing data with NIMH.
- Also, information from the assessments may be shared with the Crisis Center of Tampa Bay, Directions for Living, Children's Home Society or USF St. Petersburg Family Study Center Counseling Programs.
- It is possible, although unlikely, that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person's everyday use of the Internet. If you complete and submit an anonymous survey and later request your data be withdrawn, this may or may not be possible as the researcher may be unable to extract anonymous data from the database.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

Data Sharing

Data from this study may be submitted to the National Database for Clinical Research Related to Mental Illness (NDCT). NDCT is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share de-identified information with each

other. A data repository is a large database where information from many studies is stored and managed. De-identified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send de-identified information about your health and behavior to NDCT. Other researchers nationwide can then file an application with the NIMH to obtain access to your de-identified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDCT. The information provided to NDCT 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 NDCT data. However, you will not be contacted directly about the data you contributed to NDCT.

You may decide now or later that you do not want to share you information using NDCT. If so, contact the researchers who conducted this study, and they will tell NDCT, which can stop sharing the research information. However, NDCT cannot take back information that was shared before you changed your mind. If you would like more information about NDCT, this is available on-line at http://ndct.nimh.gov.

You can get the answers to your questions, concerns, or complaints.

If you have any questions, concerns or complaints about this study, call Dr. Alison Salloum at 813-974-1535. If you have questions about you or your child's rights, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638.

Consent to Participate and Parental Permission for My Child to Participate in this Research Study

I freely give my consent to take part and to let my child take part in this study. I understand that by signing this form I am agreeing to take part in and to let my child take part in research. I have received a copy of this form to take with me.

_____ _____

Signature of Person and Parent of Child Taking Part in Study Date

_____

Printed Name of Person and Parent of Child Taking Part in Study

Statement of Person Obtaining Informed Consent

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

Signature of Person Obtaining Informed Consent

Date

Printed Name of Person Obtaining Informed Consent