Cover Page

Official Title: Tx for Child Sexual Behavior Problems

Identifiers: NCT02625571

Document Date: August 25, 2016

1.0 Inclusion and Exclusion Criteria

1.1 Inclusion Criteria

Minor Patients

- Age 5-12 years (inclusive) with a participating consenting caregiver with legal standing to consent to treatment for the minor child. All children 7-12 years (inclusive) will be asked to provide assent. Thus, the parent-child dyad will be participating, not just the patient child. However, given that children with SBP often have co-occurring behavioral problems, such as oppositional or defiant behavior, child assent will not be required for the participation of children between the ages of 7 and 12 (see section 5.3.3.2 below).
- Sex: male or female
- A T-score > 64 on the Child Sexual Behavior Inventory (CSBI). Note that this is a standard practice measure in the child maltreatment field and is currently administered to all children between the ages of 3 and 12 who present for treatment at the TLC Clinic.
- Fluent in written and spoken English, as the assessment instruments are not available in translations and have not been validated for use with non-English speaking populations.

Adult Caregiver

- Parent or Legal Guardian of patient. Must consent to his/her own participation as well as the participation of the child.
- Self-identified as the primary caregiver (responsible for the day-to-day care of the child and who must have lived with the child for at least the last 6 months). Six months is the minimal amount of time necessary for the caregiver to validly complete the assessment measures.
- Age ≥18 years
- Sex: male or female
- Fluent in written and spoken English. See rationale above regarding measures.

In many instances of a child with SBP, a caregiver is suspected of sexually abusing the child. However, these caregivers may retain legal rights as the case progresses through the courts and usually these caregivers decline consent for the child's treatment. The TLC Clinic works closely with the PSHMC general counsel and has been directed by the general counsel to treat cases under the condition that consent is obtained from at least one caregiver/guardian with legal standing to consent to the child's treatment. This direction will also be used in the current study. Any objections by a non-custodial parent will be handled through

normal channels already in place at the TLC Clinic in collaboration with the PSHMC general counsel.

1.2 Exclusion Criteria

Minor Patients

- Age <5 or >12 years at the time of enrollment as these children fall outside of the cognitive capability and/or scientific justifications for use of the intervention under investigation.
- IQ < 70 as measured by the Kaufman Brief Intelligence Test (KBIT; Note: This measure is a commonly used instrument in the mental health field and is administered at the TLC Clinic as a point of standard care whenever concerns are raised about the cognitive ability of a caregiver or child)
- Developmental delays or severe psychiatric problems that necessitate a higher level of care than provided by outpatient treatment

Adult Caregiver

- Age < 18 years at the time of enrollment
- IQ < 70 as measured by the Kaufman Brief Intelligence Test. See above about the standard care use of this measure.
- Developmental delays or severe psychiatric problems that necessitate a higher level of care than provided by outpatient treatment
- Caregiver inability to complete assessment measures due to cognitive, psychiatric, or other limitation.
- The available caregiver is suspected or known to have perpetrated sexual abuse as indicated by police, Children and Youth Services, or another agency with authority on such matters.

1.3 Early Withdrawal of Subjects

1.3.1 Criteria for removal from study

Participants will be withdrawn from the study if safety reasons dictate a higher level of care, such as suicidal ideation or severe aggression. Clinicians utilized in this study are trained mental health clinicians capable of identifying and determining such a need. In addition, noncompliance with regular session attendance may result in withdrawal from the study. Participants are free to voluntarily withdraw from the study at any time without penalty.

1.3.2 Follow-up for withdrawn subjects

Participants withdrawn from the study either by the investigator or voluntarily will receive appropriate referral information to other providers. In the event of an emergency, appropriate emergency referral procedures in place at the TLC Clinic will be

followed. In the event of withdrawal, no further data will be collected from the participants.

2.0 Recruitment Methods

2.1 Identification of subjects

Participants will be identified through the standard referral sources currently utilized by the general clinical service at the TLC Clinic. This includes referral from the Children's Resource Center, local child protective services agencies, and pediatricians. Children meeting criteria and seeking services at the TLC Clinic will be offered the option of participating in the study. In addition to referrals, participants will also be recruited through flyers posted in within the Hershey Medical Center pediatric clinic, as well as the HMC Harrisburg 3rd street location.

2.2 Recruitment process

Patients attending the initial TLC Clinic intake assessment process complete the CSBI as standard practice at the clinic. Other information regarding the inclusion and exclusion criteria for both the child and caregiver are typically available at this intake assessment as well. The exception to this is the KBIT, however, clinicians are typically able throughout the assessment to determine if significant cognitive limitations are present. Participants who appear to meet criteria will be notified of the study and asked if they wish to participate. Those expressing interest will be provided additional information and will be notified that a member of the research team will contact them to schedule the initial assessment session. In addition to patients of the TLC Clinic, participants will also be recruited through flyers within the Hershey Medical Center pediatric clinic and the HMC Harrisburg 3rd street location, and will be instructed to call the research line to provide their contact information. A research assistant will then call the caregiver to breifly screen for inclusion and exclusion critera. Participants meeting eligibility criteria would then be scheduled for the first assessment session. At this session, the research assistant will review study procedures and document consent/assent, as well as administer the additional assessment materials not administered in the initial intake assessment (see below: KBIT, FSI, SC). Potential participants who decline participation will still be offered standard care through the TLC Clinic using standard rates and billing procedures.

2.3 Recruitment materials

Please see attached recruitment flyer text. Recruitment flyer will be created by HMC Office of Marketing and Communications.

2.4 Eligibility/screening of subjects

Participants will complete a brief phone eligibility screening. Please see attached phone screen text.

3.0 Consent Process and Documentation

3.1 Consent Process

Patient/caregiver dyads presenting to the TLC Clinic who are identified as likely meeting inclusion/exclusion criteria during the initial intake assessment will be given the opportunity to participate in the research study. Those expressing interest will be contacted by a research assistant and the first study assessment session will be scheduled at the TLC Clinic. At this first assessment session, the informed consent form will be reviewed with patients/caregivers and the opportunity to ask questions will be provided. Informed consent/assent will then be documented.

3.2 Consent Documentation

The consent process will be documented in writing with the long form of consent documentation. A member of the research team will assist in the explanation and obtaining of the written consent. A copy of the signed consent will be given to the participant and another copy will be submitted for uploading to the electronic medical record.

3.3 Consent – Other Considerations

3.3.1 Non-English Speaking Subjects

N/A: Excluded since the assessment materials used in the current study are only available in English, and have not been validated in other languages.

3.3.2 Cognitively Impaired Adults

3.3.2.1 Capability of Providing Consent

All caregivers will complete the Kaufman Brief Intelligence Test during the first study assessment. Caregivers receiving scores below 70 (intellectual disability) will be excluded from the study. Similarly, the informed consent for themselves and their child will be considered invalid and the caregiver/child will be removed from the study.

3.3.2.2 Adults Unable To Consent

Adults unable to provide consent will not be enrolled in this study. This is primarily related to the fact that their participation in reporting on the behavior of their child and their ability to implement treatment recommendations will be limited. In addition, there would be concerns regarding their ability to provide informed consent.

3.3.3 Subjects who are not yet adults (infants, children, teenagers)

3.3.3.1 Parental Permission

All children in the study will be between the ages of 5 and 12. Each child will require the consent of a legal caregiver. This will be obtained at the first study assessment session, which is the first contact with the study. In the event that a child resides with a foster or kinship caregiver, appropriate legal documents attesting to the ability of the caregiver to provide consent will be required. In some instances this may necessitate consent from an appropriate authority figure, such as Child and Youth Services caseworker or a judge. Regardless, instances where the legal caregiver is not a biological parent will be recorded along with appropriate documentation.

3.3.3.2 Assent

We will attempt to obtain assent from all child participants, regardless of age. However, we will not view assent as a requirement. Many times children with SBP have co-occurring behavioral problems including defiance and conduct problems. This may result in some children refusing to cooperate; however, removing these children from the study would significantly bias results and these children/caregivers remain in need of services despite the child's refusal. In addition, providing mental health treatment does not typically require assent from a child under the age of 14. The research assistant will explain all research procedures to children in developmentally appropriate language and solicit questions. When the child assents, the child's signature will be obtained on the consent/assent form.

4.0 Study Design and Procedures

4.1 Study Design

Participants will receive a 12-session protocol designed to ameliorate SBP among preteen children. After completing the first study assessment session, the child/caregiver dyad will be assigned to one of the two mental health clinicians participating in this trial. The clinician will then implement the protocol in weekly sessions. Assessments will be completed after every 4th treatment session, in addition to

pre-treatment and post-treatment assessments. The assessments will occur with a research assistant trained to administer the protocol. The current plan is to also collect follow-up data at approximately 4 weeks post-treatment.

4.2 Study Procedures

The treatment protocol will utilize cognitive-behavioral change techniques commonly used in standard practice and be modeled on currently available group treatment protocols for SBP that utilize similar techniques. These techniques are already standard practice at the TLC Clinic and administered in an individual format; however, this manner of delivery has not been systematically evaluated. The innovation of the current project is the definition of an individually-administered protocol, and thus the model of delivery is experimental, not the techniques. Again, even this model of delivery of techniques is standard practice in many community settings, including the TLC Clinic, even though it has not been systematically evaluated. The only distinction between standard clinical practice and the research being conducted is that the data will be more closely monitored in this project and outcome assessment will occur after every 4th session instead of the standard practice of pre and post-treatment. Participants electing not to participate will likely receive the same protocol or potentially an alternative treatment through the standard practice of the TLC Clinic. Specification of the exact order of techniques is provided below.

The measures for the protocol will be administered during defined assessment sessions by a trained research assistant after each 4th session of treatment. The next treatment session will not occur until the required assessment session takes place. All measures are described below, but each measure is either (1) a psychometric instrument assessing emotional/behavioral concerns that is standard practice at the TLC Clinic, or (2) designed to elicit information about the participant's treatment experience. It should be emphasized that each of the assessments described below are standard instruments employed at the TLC Clinic for cases of SBP, including the Child Sexual Behavior Inventory (CSBI). The exception is the Kaufman Brief Intelligence Test, which is typically only administered if there are significant concerns about cognitive ability. It is administered in this study to ensure that participants demonstrate sufficient cognitive ability to participate in and benefit from the treatment. All measures are provided in the "Supporting Documents" section. The timing of the administration of each measure is provided below.

Because each treatment session is conducted by a trained mental health clinician, concerns of safety will be identifiable each session if reported by either the caregiver or child. Mandated reporting requirements are reviewed with all TLC Clinic patients and caregivers at the initial intake assessment and, therefore, these limits of confidentiality are described to each potential participant in the current

study. In accordance with state law, concerns related to child maltreatment, homicidal or suicidal ideation will be reported to appropriate authorities.

4.2.1 Sequence of sessions

1. Initial Intake Assessment at the TLC Clinic: Potential participants are identified and recruited through standard TLC Clinic intake and assessment procedures. Those interested in participating will receive a phone call from a research assistant to schedule the first study assessment session. However, as a course of standard practice at the TLC Clinic, all patients (child and caregivers) complete the following measures during this initial intake assessment and, following informed consent/assent during the first study assessment session, these measures will become part of the study record so as to prevent needing to re-administer them during the first study assessment session:
    A. **Child Sexual Behavior Inventory (CSBI)**: The CSBI is the gold standard instrument for the assessment of sexual behaviors and SBP in children between the ages of 3 and 12 (ages inclusive; Chaffin, et al., 2008). The CSBI is a caregiver-report instrument that asks the caregiver to report on the frequency of 46 different types of child sexual behavior over the past 6 months. The CSBI is used in the majority of studies examining SBP in children (e.g., Allen, Thorn, & Gully, 2015; Friedrich, Davies, Feher, & Wright, 2003; Silovsky & Niec, 2002) and in multiple clinical trials evaluating child sexual behavior as a treatment outcome (e.g., Bonner, Walker, & Berliner, 1999; Cohen & Mannarino, 1996; Silovsky, et al., 2007). Reliability and validity of the CSBI is well-established in numerous studies with large sample sizes (Friedrich, 1997; Friedrich, et al., 1991, Friedrich, et al., 1992; Friedrich, et al., 2001).
    B. **Trauma Symptom Checklist for Young Children (TSCYC):** The TSCYC is a 90-item caregiver -report measure for children between the ages of 3 and 12 (ages inclusive) that assesses for the presence of various trauma-related symptoms and presentations, such as posttraumatic stress, dissociation, and sexual concerns. In addition to capturing constructs such as caregiver-reported posttraumatic stress, the sexual concerns scale of the TSCYC will also serve as a secondary metric of caregiver-reported SBP. The TSCYC is a widely used measure in both clinical and research contexts (Milot, Ethier, St-Laurent, & Provost, 2010; Overbeek, de Schipper, Lamers-Winkelman, & Schuengel, 2013) and reliability and validity of the TSCYC is well-established (Briere, 2005; Briere, et al., 2001; Lanktree, et al., 2008)
    C. **Trauma Symptom Checklist for Children (TSCC):** The TSCC is a child self-report measure for children between the ages of 8-16 (ages inclusive) that assesses the same constructs as the TSCYC. Children younger than 8 do not complete the TSCC; as such, all children between the ages of 8-12 in the current project will complete the

TSCC. Children are asked to report the frequency with which they experience each of 54 symptoms. In addition to providing scores for concerns such as posttraumatic stress, anger, and depression, the TSCC provides two scales assessing sexual thoughts and sexual anxiety. These scales provide a child's self-reported index of sexual concerns. The TSCC is the most widely used self-report measure of child trauma-related outcomes, with frequent use in clinical and research contexts (Allen & Berliner, in press; Allen, Thorn, Gully, 2015; Jonkman, Verlinden, Bolle, Boer, & Lindauer, 2013; Overbeek, et al., 2013) and the psychometric properties are well-researched (Briere, 1996; Crouch, Smith, Ezzell, & Saunders, 1999; Lanktree, et al., 2008).

D. **Behavior Assessment System for Children (BASC):** The BASC is a commonly used broadband caregiver-report measure that assesses various forms of internalizing and externalizing concerns as well as adaptive behavior skills. Caregivers are asked to rate the frequency with which their children display each of 160 symptoms and behaviors. The BASC is commonly used in clinical and research contexts (Allen & Berliner, in press; Barbot, Hein, Luthar, & Grigorenko, 2014; Lochman, et al., 2015) and the psychometric properties of the BASC are well-established (Reynolds & Kamphaus, 2004)

E. **Parenting Stress Index (PSI):** The PSI-Short Form is a 36-item measure that a caregiver completes to rate his/her stress in relation to parenting a specific child. The PSI is a common research instrument, used in over 1,500 research studies to assess parenting stress, with many of these studies assessing the psychometric properties of the PSI (Abidin, 1995).

2. First Study Assessment Session: This contact constitutes the first session where the child/caregiver dyad attends as a participant in the study. Either the research assistant or the PI will review the informed consent/assent form and obtain appropriate signatures. Following obtainment of informed consent/assent the following measures will be administered:

   A. **Family Sexuality Index (FSI):** The FSI was developed to assess various forms of expressed sexuality in the home, which is a strong correlate of SBP (Friedrich, 2007; Friedrich, et al., 2003). Psychometric evaluations of the FSI are not available at it is typically implemented and evaluated on an item-level basis. It is administered here in this project to evaluate the caregiver's ability to reduce expressed sexuality in the home, which is directly addressed in the treatment. Administration of the FSI is standard practice at the TLC Clinic when SBP is identified as a presenting concern.

   B. **Safety Checklist (SC):** The SC is designed to assess various caregiving and environmental variables that are linked to display of SBP among children (Friedrich, 2002, 2007). It is a semi-structured interview that assesses co-sleeping, co-bathing, family nudity, family

sexuality, exposure to sexual behavior, and caregiver monitoring of the child. These concerns are directly targeted in the current protocol and the SC is designed to evaluate the caregiver's ability to change these aspects of the family and environment. Psychometric analyses are not available at the SC is typically examined on an item-level basis. Administration of the SC is standard practice at the TLC Clinic when SBP is identified as a presenting concern.

C. **Kaufman Brief Intelligence Test (KBIT):** The KBIT will be administered to both the child and caregiver. The KBIT is a widely used brief intelligence measure that is employed in over 1,000 published research studies (Kaufman & Kaufman, 2004), and many of these studies have evaluated the psychometric properties of the measure. Collectively, these studies show that this brief measure correlates very strongly with full-length intelligence tests. Administration of the KBIT is standard practice at the TLC Clinic when concerns are raised about the cognitive ability of a child or caregiver.

3. Treatment Sessions 1-4: Sessions will occur once per week and each session is 45-50 minutes in duration. Sessions 1-4 will involve the following techniques:
   A. **Session 1:** Discussion of expressed sexuality in the family, review importance of increased monitoring of the child and discuss parenting techniques.
   B. **Session 2:** Define sexual behavior rules and consequences for breaking the rules.
   C. **Session 3:** Review the progress made in implementing the techniques from the previous two sessions. Refinement of the skills will be performed.
   D. **Session 4:** Review skills from previous sessions and discuss generalization to community settings. Practice application of the sexual behavior rules by discussing various scenarios.

4. Second Study Assessment Session: Prior to completing additional treatment sessions, the child and caregiver will attend the second study assessment session. During this assessment session the research assistant will administer the following measures:
   A. **CSBI**
   B. **TSCYC**
   C. **TSCC**
   D. **BASC**
   E. **PSI**
   F. **FSI**
   G. **SC**

5. Treatment Sessions 5-8: Sessions will occur once per week and each session is 45-50 minutes in duration. Sessions 5-8 will involve the following techniques:
    A. **Session 5:** Engage the caregiver in a discussion about beliefs regarding sex and sexuality, their opinions of what the child should know about these topics, and what the caregiver considers "healthy."
    B. **Session 6:** Provide education to the parents related to sexual behavior of children within the context of their beliefs obtained from the previous session. Review their approach to discussing these topics with the child and prepare them for discussing with the child in the next session.
    C. **Session 7:** Discuss with child what his or her questions are related to sex and sexuality. Discuss with caregiver how to respond to the questions the child raised.
    D. **Session 8:** Facilitate a discussion on sex and sexuality between the child and caregiver. This session will provide psychoeducation to the child.

6. Third Study Assessment Session: Prior to completing additional treatment sessions, the child and caregiver will attend the third study assessment session. During this assessment session the research assistant will administer the following measures:
    A. **CSBI**
    B. **TSCYC**
    C. **TSCC**
    D. **BASC**
    E. **PSI**
    F. **FSI**
    G. **SC**

7. Treatment Sessions 9-12: Sessions will occur once per week and each session is 45-50 minutes in duration. Sessions 9-12 will involve the following techniques:
    A. **Session 9:** Teach the child and caregiver impulse control skills focused on increasing tolerance and control of impulses.
    B. **Session 10:** Review skills from the previous session and refine as needed.
    C. **Session 11:** Teach the parent sexual abuse prevention skills. This includes reviewing what has already been discussed and what still needs to be addressed. These skills will be reviewed with the child.
    D. **Session 12:** Process the child's desire to engage in sex (if present), examine the peer group and the role parents can play in encouraging positive peer relationships.

8. Fourth Study Assessment Session: This session represents the post-treatment assessment and the child and caregiver are both expected to attend. During

this assessment session the research assistant will administer the following measures:

A. **CSBI**
B. **TSCYC**
C. **TSCC**
D. **BASC**
E. **PSI**
F. **FSI**
G. **SC**
H. **Caregiver Satisfaction Questionnaire (CSQ):** The CSQ is a commonly used process outcome measure that asks caregivers to rate their treatment experience on various aspects of the clinical process. Psychometrics are not available as the CSQ is typically evaluated on an item-level basis.
I. **Therapeutic Alliance Scale for Children (TASC):** The TASC is another commonly used process outcome measure that assesses the child's perception of their relationship with the clinician. The TASC is typically evaluated on an item-level basis.

9. Fifth Study Assessment Session: Approximately 4 weeks after the completion of treatment, children and caregivers will be expected to participate in a follow-up assessment to determine whether treatment improvements are maintained. This will constitute the participants' final contact with the project. During this assessment session the research assistant will administer the following measures:
   A. **CSBI**
   B. **TSCYC**
   C. **TSCC**
   D. **BASC**
   E. **PSI**
   F. **FSI**
   G. **SC**

7.2.2: Recording of sessions: All treatment sessions will be videorecorded and reviewed by the PI to ensure treatment fidelity. The clinician will identify which number sessions is being provided and the PI will watch the session to ensure that all treatment elements for that numbered session were delivered by the clinician. The research parent/caregiver and child will be seen only by the PI and the images will not be used outside of this assessment of treatment fidelity. As such, there is no data derived from this process that is attached to any participant/patient's chart and sessions are not transcribed. No database using any confidential information or PHI is established for this purpose. All videorecordings are digital and use the standard system developed by the PSHMC IT department. All recordings are storedelectronically behind the PSHMC firewall. These recordings are not attached to patient charts and are deleted after being reviewed. Alternatively, depending on schedules, the PI may observe live sessions to

monitor fidelity, in which case no recordings will occur. All cameras and recording equipment are already installed at the TLC Clinic and it is common TLC Clinic practice to record sessions for the purposes of training and clinician supervision. All patients are notified of this at the initial intake assessment.

7.2.3: Treatment disrupting events: Clinicians will document any treatment disrupting events (e.g., inpatient admissions, protective services reports) in progress notes completed after each phone call and/or treatment session. These notes will be reviewed following completion of the patient's participation in the project and such events will be coded for inclusion in analyses.

4.3 Duration of Participation

Each participant is expected to complete the treatment protocol of 12 weekly sessions, in addition to each of the 5 assessment sessions. Pre-treatment and post-treatment assessments are standard practice at the TLC Clinic to evaluate progress; the assessments at each 4 week time point and the follow-up assessment are unique to this study.

Statistical Plan

Sample size determination

A convenience sample of 15 child/caregiver dyads. Ethnic and gender composition will likely reflect the current composition of the TLC Clinic (45% White, 45% African-American, 10% other ethnicities; 60% female, 40% male).

The current project is designed to pilot the intervention for feasibility and functionality. This is within the normal limits of Phase 1 protocol development for behavioral interventions.

Statistical methods

Primary statistical analysis will be dependent on the variability and distributions of outcome metrics. It is anticipated that significant positive skew will be observed for many of the outcome metrics. Given this and the small sample size, nonparametric analyses will likely be employing, primarily the Friedman test. However, outcome metrics meeting assumptions of normality may be subjected to t-tests or repeated measures ANOVAs with potential modifications employed for derivation of confidence intervals (e.g., bootstrapping). Other general linear model analyses may be utilized depending on statistical diagnostic results.