

## Trauma-focused cognitive-behavioural therapy for children: A study of process and outcome.

Given the high prevalence of Post-Traumatic Stress Disorder (PTSD) in childhood, and the current under-treatment of children and adolescents who develop PTSD, effective treatment models for this population is needed. The proposed project is a multi-site treatment outcome study for children and adolescents 10-18 years old who have been exposed to traumatic incidents and developed PTSD related symptoms. This randomized controlled trial will examine the short and long-term effects of trauma-focused cognitive-behavioural therapy as developed by Judy Cohen, Anthony Mannarino and Esther Deblinger (2006) on youth exposed to serious trauma, and moderating factors on treatment outcome. Also cost-benefit assessments will be conducted. More knowledge within this field is important for practitioners as well as policy makers in planning interventions and therapy for children and their caregivers.

### Background

Children experiencing traumas, such as sexual abuse, physical abuse, domestic violence, serious accidents, or natural disasters, may develop severe health problems. The impact of trauma in children has been studied in a wide range of situations, such as burns (Saxe *et al.*, 2005), traffic accidents (Winje & Ulvik, 1998), child sexual abuse (Cohen & Mannarino, 1998), community violence (Kilpatrick *et al.*, 2003), and natural disasters (Dyb & Jensen, In Prep; Jensen & Dyb, In Prep; Pynoos *et al.*, 1993). Posttraumatic stress reactions are the most commonly reported symptoms of psychological distress after traumatic experiences. Studies have documented that children exposed to violence (Kilpatrick *et al.*, 2003), accidents (Stallard, Velleman & Baldwin, 2001), war traumas (Ajdukovic, 1998), abuse (Ackerman, Newton, McPherson, Jones & Dykman, 1998), 1996), chronic illness (Connolly, McClowry, Hayman, Mahony & Artman, 2004), and catastrophes (Goenjian *et al.*, 2001) may develop PTSD. As in adults, PTSD in children and adolescents is a highly comorbid condition, often associated with anxiety and mood disorders (Ackerman *et al.*, 1998). Traumatized youth with PTSD may also display severe behaviour problems (Saigh, Yasyk, Oberfield, Halamandaris & Mc Hugh, 2002), and substance abuse (Clark *et al.*, 1995). Hence, traumatic experiences may not only induce posttraumatic stress reactions, but also psychosocial impairments in a vulnerable period of life.

The development of PTSD depends on the traumatic event, such as the characteristics of the event (Pynoos *et al.*, 1993), the child's proximity to the event, and the child's subjective experience of the event (Bryant, Mayou, Wiggs, Ehlers & Stores, 2004), including perceived life threat and loss (Vernberg, La Greca, Silverman & Prinstein, 1996). However, development of PTSD after traumatic events also may depend on biological, psychological, and social factors present prior to the event. Other pre-trauma variables of special interest in the etiology of PTSD, are events that have previously produced distress in the child's life, e.g., adverse life events and prior traumas (Neuner, Schauer, Catani, Ruf & Elbert, 2006). The resulting distress may increase in an additive fashion. Studies have shown that recurrent traumas increase the risk of developing severe pathology and particularly interpersonal traumas may have a detrimental influence on a child's development (Dube, Felitti, Dong, Giles & Anda, 2003).

The impact of the family may also affect the child's development after trauma. In response to shared traumatic experiences, a relationship between parental and child distress has been found in wars (Dawes, Tredoux & Feinstein, 1989), technical disasters (Green *et al.*, 1991), and fires (Jones, Ribbe, Cunningham, Weddle & Langley, 2002). Studies have also documented the impact of parental emotional reaction and parental support on the development of PTSD in children. In a longitudinal study Lynskey and Fergusson



(1997) found that lack of parental support predicted distress in 18 year olds who had been sexually abused during childhood. This relationship has also been found in studies on community violence (Burton *et al.*, 1994), in cases of parental homicide (Burman & Allen-Meares, 1994), in child maltreatment studies (Kolko, 1996), and in cases of incest (Cohen & Mannarino, 1998).

### **Prevalence of child trauma**

Prevalence studies on the number of Norwegian children experiencing different types of trauma are nonexistent. Three national surveys exploring the prevalence of child sexual abuse revealed rates between 2.8 % and 22% depending on the definitions used (Mossige & Stefansen, 2007, Sætre, Jebsen & Holter, 1986; Tambs, 1994). A recent study involving 7033 eighteen to nineteen year olds in Norway reported that 20 % girls and 14 % boy had experienced at least one violent episode of child physical abuse by a parent where approximately 2% reported being beaten more than ten times during childhood, and 10 % of the youth reported witnessing at least one violent episode between parents (Mossige & Stefansen, 2007). The prevalence rates for how many children and adolescents in Norway that have experienced other types of trauma, such as accidents, sudden death of a family member, or war related traumas in refugee children, are not known. Prevalence rates from the U.S.A. show, however, that approximately 25 % children and adolescents have experienced at least one serious traumatic incident before they have reached the age of 16 (Costello, Erkanli, Fairbank & Angold, 2002).

Taken the vast number of children that predictably will be exposed to serious trauma during their childhood and the detrimental effects such trauma may have on a child's mental health and development, psychological treatment for this group of children is often necessary. Studies have also shown that treating adults for childhood traumas is very difficult, and early intervention is recommended. A survey conducted by the Norwegian Centre for Violence and Traumatic Stress Studies, showed that a large proportion of the referred children and adolescents to child guidance clinics had been traumatized. Almost none of the interventions that were given to the referred children were trauma focused, and many therapists did not feel that they were able to give adequate help to this group of children. The therapists expressed a need for training in efficient methods for working therapeutically with strongly traumatized children. In Norway controlled studies on possible effects of treatment for traumatized children and adolescents are non existent.

### **Psychotherapy studies of children and adolescents**

In the international community, studies on child and adolescent therapy are few compared to adult studies. Despite some progress, several key areas have been neglected in child therapy research in general. These areas of neglect are related to 1) the lack of effectiveness studies i.e. studies conducted in regular clinics, 2) research where evidence based treatments are compared to usual clinical care, and 3) research on the mechanisms of change, such as the impact of the therapeutic alliance (Kazdin, 2004, Weisz & Gray, 2007).

*Effectiveness studies:* The current research literature on evidence based treatments for children and adolescents reveals that very few studies have been conducted in real-world practice conditions. In fact, a review by Weisz & Gray (2007) revealed that only 1% of the studies reviewed included some clinically referred children, practicing clinicians, and were conducted in actual clinics. Thus the studies provide relatively little knowledge about how evidence based treatments work under conditions of everyday clinical care.

*Evidence based treatments vs usual care:* Another concern in the psychotherapy research is the limited number of studies that have actually compared a target treatment with usual care or treatment as usual. Do evidence based treatments actually provide better treatment outcomes than usual care? Despite how crucial the answer to this question is for treatment management and planning, very few randomised comparisons of evidence based therapies have been compared to usual care (Weisz, Jensen-Doss & Hawley, 2006). From a clinical policy perspective the evidence therefore is not conclusive that treatment as usual should be replaced with evidence based treatments within a wide range of clinical problems.



*The therapeutic alliance:* In adult studies on therapy outcome, the development of a positive alliance has proven to be one of the most consistent predictors of successful therapy across a wide range of psychological problems and therapeutic orientations (Orlinsky, Rønnestad & Willutzki, 2004). There has however been little research on the working alliance in child psychotherapy (Eltz, Shirk & Sarlin, 1995; Shirk & Karver, 2003). To our knowledge only one study has examined the therapeutic alliance in therapy with traumatized children (Jensen et al. Submitted).

*Cost benefit analysis:* Another important issue for policy makers and practitioners is the issue of resources. Compared to other fields in public health, the child trauma related economic evaluation literature is limited (Corso & Lutzker, 2006). Since resources have alternative uses, it is essential to find out how the effect of a treatment compares with its cost. In this study we have started a collaboration with Professor in economics Tor Iversen and Associate professor in economics Eline Aas at The Medical Faculty, UiO. They will do a cost benefit analysis from the study. From a social point of view a cost is equal to the benefit from a resource in its best alternative application (opportunity cost). When certain conditions are fulfilled the opportunity cost equals cost as it may be observed in the market. Without markets a cost has to be calculated to imitate the opportunity cost. Studies that have looked at the relative cost of an intervention are scarce. Health benefit relative to cost in principle can be compared between a variety of diseases. In particular we have the opportunity to compare the health benefit relative to resource consumption between the two arms of the randomized study in addition to other treatments where data are available. The potential of this study is to contribute to a more informed policy debate about optimal allocation of resources in mental health care for children and perhaps also in an even broader perspective.

#### **“State of the art treatment” for traumatized children and adolescents**

The aforementioned lack in research in child psychotherapy in general is even more striking in the child trauma therapy literature. Controlled treatment studies on traumatized youth are limited, and there is therefore inadequate empirical support for various treatment methods (Cohen, Berliner & Mannarino, 2000). The treatment method that has received the most empirical support is Trauma-Focused Cognitive Behavioural Therapy (TF-CBT). TF-CBT has to date been studied in six randomized controlled trials all showing that TF-CBT had better outcomes than the control groups (Cohen, Deblinger, Mannarino & Steer, 2004; Cohen & Mannarino, 1998; Cohen & Mannarino, 1996, 1997; Cohen, Mannarino & Knudsen, 2005; Deblinger *et al.*, 1996; Deblinger, Mannarino, Cohen & Steer, in press; Deblinger, Stauffer & Steer, 2001; King *et al.*, 2000). None of these studies have, however, been conducted outside of the United States, nor have they been administered in regular clinical settings, nor have they been contrasted with treatment as usual. The relative importance of the therapeutic alliance in predicting outcome has not been studied either, and no studies have assessed cost-effectiveness.

#### **Trauma-Focused Cognitive Behavioural Therapy model**

The Trauma-Focused Cognitive Behavioural Therapy model (TF-CBT) was originally developed for treating children who had been sexually abused. It has later been tested on children experiencing multiple traumas, children exposed to domestic violence, childhood traumatic grief and children exposed to the September 11<sup>th</sup> terror attack (Cohen, Mannarino, Murray & Igleman, 2006).

TF-CBT is a short term intervention consisting of 12 to 15 sessions. The model integrates cognitive behavioural, interpersonal, and family therapy principles with trauma interventions. The interventions target specifically PTSD symptoms, such as depression, anxiety, trauma-related shame, and trauma-related maladaptive cognitions. Developing a trauma narrative aids the therapist in identifying cognitive distortions and helps the child overcome avoidance to trauma reminders. The method also includes a parenting component which enhances parental support, decreases parental distress, and improves positive parenting practices. The model is manualized through providing a general structure where components are provided in a specific order. At the same time flexibility in adapting the model to the particular child and family is encouraged (Cohen *et al.*, 2006).



## Research questions

In this study we seek to investigate whether TF-CBT results in better outcomes for traumatized youths than the treatment that is commonly provided in regular clinical practice in Norwegian child guidance clinics. Also the importance of parental support and the therapeutic alliance will be studied. Lastly the study will employ a health economic perspective. In this study costs will be measured by detailed registration of therapeutic time and other resources that are devoted to the sessions and treatment.

The main research question is:

- Is TF-CBT more effective than treatment as usual in regular clinics?

The secondary research questions are:

- Are there any effect differences between types of trauma?
- What role does the therapeutic alliance play in predicting drop-out and outcome?
- What role does parental support play in outcome?
- Is TF-CBT more cost efficient than treatment as usual?

## Method

This is primarily an effectiveness study. The study will use a random control design, and will be implemented in regular clinical practice. Therapists from three child guidance clinics in Norway are participating. A total of 125 cases will be randomly selected to either a TF-CBT treatment group or a TAU treatment group.

Power analysis:

Similar intervention studies with TF-CBT have found differences between intervention group and other treatment of about 0.5 SD. Estimating similar effect size of 50 % in this study, we will achieve a power of 0.80 with 62 participants in each group and an alpha of 0.05.

*Inclusion criteria:* Children between the age of 10-18 referred to the guidance clinic, and who have experienced trauma, and who present with post traumatic stress symptoms. Participants and the primary caretaker must be able to speak Norwegian.

*Exclusion criteria:* Severe psychosis or severe mental retardation. The youth must not have had *severe* conduct disorders previous to the trauma experience.

*Procedure:* Normal referring procedures to the clinic will be followed. Once the case is admitted to the clinic and consent to participation in the study is given, pre-treatment assessment is conducted by a clinician not employed at the clinic. If the child fulfils the inclusion criteria, the case is randomly assigned to either a treatment as usual group or a TF-CBT group. It is important that the person testing is blind to what kind of treatment the family is receiving. After the pre-treatment assessments, new assessments will be conducted after the 6<sup>th</sup> session for both groups. For the treatment as usual group treatments that last more than 15 sessions, continuing assessments will be conducted every 15<sup>th</sup> session till therapy terminates. Post-treatment assessments will be taken at treatment completion for both groups. Follow-up assessments will be conducted one year and three years after treatment termination for both groups.

All the sessions will be audio-recorded in order to control for treatment fidelity. In the TF-CBT group, treatment fidelity will be checked by reviewing all the recordings of the therapy sessions. In the treatment as usual group sessions will be checked randomly to assure that the therapists are not performing core aspects of TF-CBT. A researcher will also review the tapes in order to determine what kind of therapeutic interventions are being used in the treatment as usual group.

## Recruitment

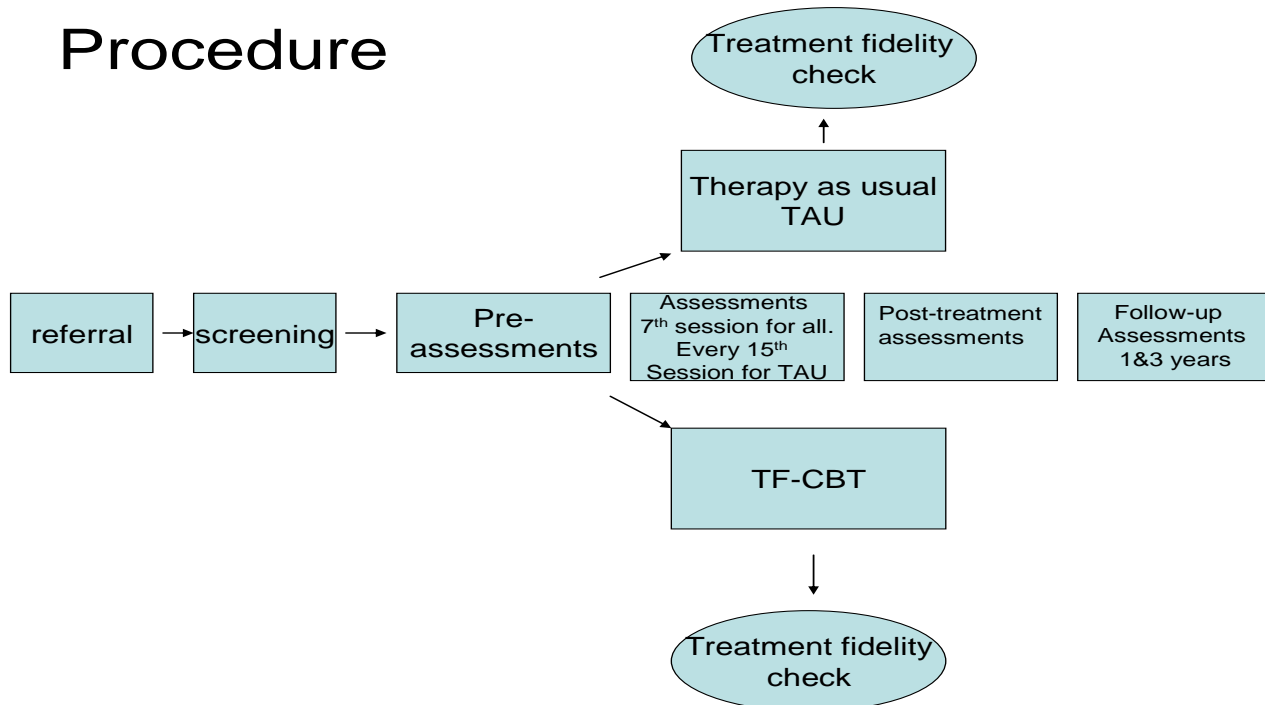
Seven child guidance clinics have been recruited: Grorud barne- og ungdomspsykiatiske poliklinikk, Bærum barne- og ungdomspsykiatiske poliklinikk, Nic Waal barne- og ungdomspsykiatiske poliklinikk, Bodø barne- og ungdomspsykiatiske poliklinikk, Holmestrand barne- og ungdomspsykiatiske poliklinikk, Tønsberg barne- og ungdomspsykiatiske poliklinikk, and Larvik barne- og ungdomspsykiatiske poliklinikk. Recruitment of trauma cases started April 1, 2008.

## Training



Seventeen therapists have completed training in TF-CBT. The therapists have received training by the developers of the model, Judy Cohen and Anthony Mannarino, by supervisor Laura Murray and by the project leader Tine K. Jensen. The therapists have in addition completed a web based learning course. Throughout the study the therapists will receive continual supervision and a continuing training collaboration and consultation team with Cohen and Mannarino is established. Treatment and training protocols have been made.

## Procedure



### Measures:

All the instruments have established acceptable psychometric properties. All the measures have been translated to Norwegian in collaboration with the developers.

### Children's measures:

**CPSS (Child PTSD Symptom Scale):** (Foa, Johnsen, Feeny & Treadwell, 2001) is the child version of Posttraumatic Diagnostic Scale (PTSD). The self-report measure consists of 17 items and assesses the frequency of all PTSD symptoms within the past month.

**CAPS-CA (Clinician-Administered PTSD Scale):** (Nader et al., 1996). A semi-structured interview consisting of 36 items designed to assess the essential features for Posttraumatic Stress Disorder as defined by DSM-IV, Acute Stress Disorder and associated features of the diagnostic syndrome (e.g. survivor guilt).

**SCARED (Screen for Child Anxiety Related Disorders)** (Birmaher, Khetarpal, Cully et.al, 1999) A 41-item self-report measure of child anxiety. It indicates the presence of any anxiety disorder, and can also specify if it is a *Panic Disorder or Significant Somatic Symptoms, Generalized Anxiety Disorder, Separation Anxiety Disorder, Social Anxiety Disorder or Significant School Avoidance*.

**cPTCI (Child Post-Traumatic Cognitions Inventory)** (Meiser-Stedman, Smith, Yule & Dalgleish, 2003): Is a 25 item self-report that measures dysfunctional thinking as permanent & disturbing change, and the impression of being a feeble person in a scary world.

**SDQ (Strengths and Difficulties Questionnaire):** The SDQ is a brief behavioural screening questionnaire consisting of 25 items covering four problem domains (*emotional problems, conduct problems, hyperactivity problems, peer problems*) as well as personal strength (*prosocial behaviour*).

**MFQ (The Mood and Feelings Questionnaire)** (Angold et. al 1987). The MFQ is a self-report measure of depression designed for children ages 8 to 18. It consists of a series of 34 descriptive phrases regarding how the subject has been feeling or acting recently. The questionnaire measures both the full range of DSM IV diagnostic criteria for depressive disorders, as well as additional items reflecting common affective, cognitive, and vegetative features of childhood depression.



**QUALITY OF LIFE QUESTIONNAIRE (16D©)** (Apajasalo et al. 1996) A questionnaire developed for measuring present health status. The health state descriptive system includes 16 dimensions (mobility, vision, hearing, breathing, sleeping, eating, speech, elimination, school and hobbies, mental function, discomfort and symptoms, depression, distress, vitality, appearance and friends).

*Therapeutic alliance scale (TASC)*: (Shirk & Saiz, 1992). A self-report questionnaire consisting of 12 items that measures the therapeutic alliance. There is a therapist scale that is filled out by the therapist and a child scale that the child fills out.

### **Parental measures:**

*The UCLA PTSD Index for DSM-IV Parent Report Version (UCLA Index)* (Steinberg, Brymer, Decker & Pynoos, 2004): a 21-item instrument for the parent to report the child's PTSD symptoms.

*Strengths and Difficulties Questionnaire Parent Version (SDQ)*: The SDQ is a brief behavioural screening questionnaire consisting of 25 items covering four problem domains (*emotional problems, conduct problems, hyperactivity problems, peer problems*) as well as personal strength (*prosocial behaviour*).

*Parental Emotional Reaction Questionnaire (PERQ)*: (Mannarino & Cohen, 1996). A parent self-report measure for emotional distress related to the child's experience.

*Parental Support Questionnaire (PSQ)*: (Mannarino & Cohen, 1996). A self-report measure on parental support and attributions about responsibility.

*Center for Epidemiologic Studies Depression Scale (CESD)* (Radloff 1977) A 20 item self-report measure on depression intended for the general population.

*The Working Alliance Inventory (WAI), therapist and client version*: (Horvath & Greenberg, 1989). A self-report measure that consists of 36 items and has three subscales; Therapeutic bond, agreement on tasks and agreement about goals. The measure will be administered to the therapist, and the parents.

### **Project leadership and organization**

The study will be conducted at the Norwegian Centre for Violence and Traumatic Stress Studies. The research group at NKVTS consists of: Project leder Tine K. Jensen; Doktoralt kandidater Silje Ormhaug and Tonje Holt; Post doctoral candidate, Silje Hukkelberg; Specialists in clinical psychology; Shirley Stormyren and Live Hoaas; and research coordinator Karina Saksberg.

Dr. Psychol Tine K. Jensen leads the project. Jensen is a specialist in clinical child psychology. Her doctoral work was on therapeutic interventions on cases where child sexual abuse was suspected (Jensen, 2005). She has also previous experience from psychotherapy research from a study conducted at University of Maryland, School of Medicine, where she was a visiting scholar working with Dr. Catherine Koverola at a research clinic for traumatized children. In this study the effect of individual and family therapy for abused children was compared. The last two years she has been the lead researcher of a longitudinal interview study on children traumatized by the tsunami, where 145 children and 89 parents were interviewed in their homes. Jensen has also visited the Center for Traumatic Stress in Children & Adolescents at the Allegheny General Hospital in Pittsburg and has started a research and treatment collaboration with Judy Cohen and Anthony Mannarino. Jensen is now employed at NKVTS, and is an associate professor at the Psychology Department at the University of Oslo.

Shirley D. Stormyren and Live Hoaas are specialist in clinical psychology, and responsible for treatment fidelity testing and clinical supervision.

Professor Tor Iversen and Eline Aas at the Faculty of Medicine are co-investigators on the cost-benefit part of the study. Tor Iversen is cand. oecon. and dr. polit. from University of Oslo. Since 1993, Iversen has been employed by the Institute of Health Management and Health Economics, from 2001 as professor of health economics. He is one of the initiators of Health Economics Research programme at the University of Oslo (HERO). From August 2006 he is Director of Research of HERO. Iversen has been a visiting scholar at the University of York, and University of California, Berkeley.



Eline Aas is a Health Economist, at the Institute for Health Management and Health Economics, University of Oslo, and HEHØ (Economic evaluation in Helse Sør-Øst), Aker University Hospital. She has since 2000 worked with economic evaluation as a researcher, teacher and counsellor of different projects for researchers in the hospitals in Health Sør-Øst.

### **National cooperation**

Professor Helge Rønnestad at the Psychology Department in Oslo is a leading researcher on psychotherapy studies both nationally and internationally. He has consented to supervise the research group.

### **International cooperation**

The research group has established a close collaboration with the developers of TF-CBT, Judy Cohen and Anthony Mannarino, at the Center for Traumatic Stress in Children & Adolescents at the Allegheny General Hospital in Pittsburg. This team will provide training as well as ongoing case consultation.

Dr. Stephen Shirk at Denver University is a leading researcher on child psychotherapy. He has also developed the Therapeutic Alliance Scale for Children (TASC) that will be used in the study. He will function as advisor in design, implementation and analysis.

### **European network**

A collaboration is initiated with Dr. Lutz Goldbeck at the Department for Child and adolescent Psychiatry at the University of Ulm in Germany. Dr. Goldbeck and his staff are planning a similar study only aimed at children that have experienced traffic accidents. At present the collaboration is on coordinating which measures will be used in each study, discussing design, and implementation. A broader European network is planned.

### **Ethical issues.**

The study is recommended by the Regional Ethical Committee, and approved by the Norwegian Social Science Data Services. Participant consent will be provided by the child and the child's caregivers. Access to therapy at the clinics will not be contingent on participation in the study.

### **Dissemination**

The results of the proposed trial will enhance the implementation of trauma-specific treatments in Norwegian community settings, where they are most needed and will have the broadest impact. The movement of a clinical trial into service settings, will substantially increase the external validity of the treatment, a common concern of efficacy studies implemented solely within academic settings. The participating mental health service providers in the proposed study will improve their expertise in diagnosis and treatment of PTSD, and a better awareness for the identification of post-traumatic stress disorders in children will be established within the healthcare system, with the consequence of providing more early psychosocial interventions for the children in need. Thus, it can be assumed that this study will initiate a significant improvement of timely identification and treatment for this population.

Results from the study will be published in national and international journals. Both broader journals within child mental health, and more trauma related journals will aid in the increase the professional awareness of the results. In line with recent guidelines, this study is registered in an approved clinical trial registry to ensure that the results will meet the requirements to be published in high ranking peer-reviewed journals. Results will also be presented at national and international conferences.

Several of the researchers have extensive teaching obligations at Norwegian universities and the results will be used in teaching students. The research team has agreed to teach the remaining clinicians at the participating clinics in the model after the study is conducted. In this way we aim to spread the method so that more therapists may use the model. An implementation plan for a broad based implementation in clinics throughout the country is in preparation. We will adapt the implementation manual for TF-CBT, *How to Implement Trauma-Focused Cognitive-Behavioral Therapy*. This manual was developed by two task forces of the



National Child Traumatic Stress Network. Knowledge from the study will be used to make cultural adaptations to the model.

This study is important for several purposes. First of all many Norwegian children and adolescents are expected to experience serious trauma during their childhood. Many of these children will develop severe long-term psychological problems if they do not receive adequate therapy. More knowledge about what models for treatment produce best results is therefore essential. Second, this is the first random control study on TF-CBT for children in mental health clinics to be conducted in Europe. Knowledge about how the method can be implemented in other countries outside The United States and what, if any, cultural differences need to be taken into consideration will be of importance also for other European countries. Third, the model has not been tested in regular clinical settings before. Therefore, we do not know whether to expect the same effect, nor if it is feasible to implement the model in regular clinics. The naturalistic design used in this study will therefore provide new insights. Forth, studies on psychotherapy show that treatment effects may also be due to the quality of the relationship between the therapist and client rather than the treatment method in it self, and studies on the mechanism of change and the influence of the therapeutic alliance on change process are therefore sought after. Including measures on the therapeutic alliance in child trauma studies has not been done before. Perhaps most important are the clinical implications the study may have. Provided that the TF-CBT model shows good effect, there is a long term ambition that the method can be taught to therapists and implemented in clinics over the country. Because TF-CBT uses some techniques many Norwegian therapists are familiar with, and because it is a short term intervention that is possible to give within the resources normally provided in child outpatient clinic, there is reason to believe that implementing this method in regular clinical practice is feasible. Fifth, little is known of the cost-effectiveness or cost-benefit of therapy for traumatized children. For treatment planners and policy makers more knowledge on the costs associated with interventions may provide for more efficient services.

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