

Identification and treatment of children exposed or subjected to intimate partner violence or child abuse in Sweden

Submission date 23/12/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 16/02/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/09/2014	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

When children experience violence in their families, they are at risk for developing psychiatric symptoms. Some of these children will be depressed, anxious, behave destructively, or could be haunted by the memories from the family violence. In child mental health care clinics (CAM), children with these experiences seem to be a large group. In order to offer good quality care, we need to know more about the experiences of violence of these children and their parents. We also need to evaluate treatments in order to recommend treatment models more generally within CAM. We need to be better in assessing the violent situations children and parents are facing.

Who can participate?

Children who have been exposed to direct violence from parents or other caregivers or have witnessed violence between parents or other caregivers can participate in the study. In addition, the child should suffer from psychiatric symptoms.

What does the study involve?

When children and parents attend our clinic, we will routinely ask if violence occurs in the family. We ask both about violence directly against the child from the caregivers, but also if parents have been violent against each other. By this practice, we will know how common family violence is among our clients. We will assess how dangerous or insecure the situation is in the family. If violence has occurred in the family, they will be offered to participate in the study. Children between 5 and 8 years of age will be asked to participate if they have symptoms closely related to the experience of violence (trauma reactions). Children between 9 and 17 years old will be asked to participate if they have trauma reactions or any other symptoms like depression, anxiety or behavior problems. Children with trauma reactions will be randomly allocated to receive either Trauma-Focused Cognitive Behavior Therapy (TF-CBT) or ordinary psychiatric treatment. We think the effect on childrens trauma symptoms will be stronger with TF-CBT compared to ordinary treatment. In this treatment, the child will learn how to cope with negative memories and experiences. They will also be able to learn more about their body reactions, social skills, and how negative thinking affects their life. Children with other

symptoms will be randomly allocated to receive either a family therapy called Attachment Based Family Therapy (ABFT) or ordinary psychiatric treatment. In ABFT the aim is to create a better and trustworthy relationship between the child and the parents. We think the relation between the child and the non-abusive parent will be better with this treatment compared to ordinary treatment. TF-CBT and ABFT will last for about one term, i.e. 10 -15 sessions, each session lasting 90 minutes. Ordinary treatment will vary in length and frequency. Parents or other caregivers will always be engaged in the child's treatment. Treatment is offered to the patient and his/her non-abusive parent. The abusive parent is offered one individual session before treatment starts and one when treatment is finished. If he/she wants help he/she is referred to other services.

What are the possible benefits and risks of participating?

When focusing on the situation of violence we are aware that this might cause emotional arousal or could put the family into an uncomfortable or dangerous situation. This is the reason why we are conducting the thorough risk and safety assessment. We are also cooperating with child protection officers in order to safeguard the children and the abused parent.

Where is the study run from?

The treatment is carried out at BUP Gamlestaden, in Sweden - a child and adolescent mental health clinic.

When is the study starting and how long is it expected to run for?

The study ran from January 2012 to December 2013.

Who is funding the study?

The study is funded by The Crime Victim Compensation and Support Authority, The Swedish Council for Working Life & Social Research, and Children's Welfare Foundation Sweden.

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Identification and treatment within the Swedish Child and Adolescent Psychiatry Services of children exposed or subjected to intimate partner violence or child abuse: a randomised controlled trial

Study objectives

Trauma-focused cognitive behavior therapy (TF-CBT) has better effect on trauma symptoms and /or general mental illness compared to treatment as usual (TAU) in child and adolescent patients with severe post traumatic symptoms.

Attachment based family therapy (ABFT) has better effect on attachment and general mental illness compared to TAU, in patients without severe post traumatic symptoms, but who meet the criteria for at least one other psychiatric diagnosis (primarily mood, anxiety, or conduct disorders).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethical Review Board, Gothenburg, Sweden, 25/03/2011, ref: 166-11

Study design

Randomized controlled single center study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Children subjected to intimate partner violence or child abuse with at least one confirmed DSM-IV diagnosis

Interventions

Two subgroups of violence exposed children; with and without severe trauma reactions:

Cohort I: children with severe trauma reactions receive Trauma-focused cognitive behavior therapy 10-15 sessions or treatment as usual individually accommodated.

Cohort II children with other psychiatric diagnosis receive Attachment based family therapy maximum 17 weeks or treatment as usual individually accommodated.

Follow up assessments at the end of treatment and one year from treatment start.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

For children in Cohort I:

Trauma-symptoms and frequency of psychiatric symptoms and DSM-IV diagnosis

For children in Cohort II:

Attachment ruptures and frequency of psychiatric symptoms and DSM-IV diagnosis

Key secondary outcome(s)

1. Psychological well-being in children
2. psychiatric symptoms in parents
3. Parenting competency
4. Therapeutic alliance

Completion date

31/12/2013

Eligibility**Key inclusion criteria**

1. Patients attending child psychiatric services exposed to intimate partner violence or child abuse as measured by the revised Conflict Tactics Scale 2 (CTS2) or child version (CTS-C).
2. At least one item on CTS2 or CTS-C positively checked on sexual abuse or at least three items checked on physical violence or at least five items checked on psychological abuse. Even if five items is checked, when at least one physical item is checked, the patient will be included.
3. Younger children will be included on parent reporting about child abuse.

Cohort I: Consecutively enrolled patients from five to seventeen years of age subjected to child abuse or intimate partner violence. In the age span five to eight years with at least four criteria fulfilled from the PTSD-diagnosis according to DSM IV. In the age span nine to seventeen years five criteria is required with at least one from each cluster (re-experience, avoidance, arousal).

Cohort II: Consecutively enrolled patients from nine to seventeen years of age subjected to child abuse or intimate partner violence and diagnosed according to DSM IV (except PTSD).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

1. Mental retardation (intelligence quotient (IQ) less than 70
2. If the child or parent need an interpreter to fulfill treatment
3. Absence of a parent to take part in the treatment
4. If the child needs inpatient treatment
5. Pervasive developmental disorder

Date of first enrolment

01/01/2012

Date of final enrolment

31/12/2013

Locations

Countries of recruitment

Sweden

Study participating centre

BUP Gamlestaden

Gothenburg

Sweden

415 02

Sponsor information

Organisation

The Crime Victim Compensation and Support Authority (Sweden)

Funder(s)

Funder type

Government

Funder Name

The Crime Victim Compensation and Support Authority (Sweden)

Funder Name

Childrens´ Welfare Foundation (Sweden)

Funder Name

Swedish Council for Working Life and Social Research (Sweden)

Alternative Name(s)

Swedish Council for Working Life and Social Research, FAS

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Sweden

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration