Trial Description

Title
Implementation and Evaluation of a Needs- and Community-Based Managed Mental Healthcare for Children and Adolescents after Abuse and Neglect - Case-Management Intervention Study

Trial Acronym
CANMANAGE

URL of the trial

Brief Summary in Lay Language
Victims of child abuse and neglect (CAN) have a high risk to develop a variety of chronic mental disorders. So far, many survivors of CAN have untreated mental health problems, although there are proven treatments. Untreated trauma-related mental disorders put significant burden on the individual and produce considerable costs for the society. Therefore a group of researchers from child and adolescent psychology and psychiatry developed the CANMANAGE project to combine an intervention that aims to improve access to proven treatments for those CAN survivors. The study enrols 152 CAN victims aged 4-17 years and their non-offending caregivers at four German communities. Efforts will be directed to include children known to be on elevated risk for mental disorder due to CAN, such as foster children, children in group homes, or children from migrant families. All study participants receive a thorough assessment of their trauma history and their current mental health state. It is planned to test the effectiveness of a specialized intervention model (case management) to improve access and adherence to proven treatments. A case manager will help those children in need and their families to find the right treatment and to accomplish the treatment successfully. Comparisons to children who do not receive the assistance by a case manager will demonstrate whether the intervention aimed at improving timely utilization of mental healthcare is effective.

Brief Summary in Scientific Language
Victims of Child Abuse and Neglect (CAN) have an elevated risk to develop mental disorders. To date, many survivors of CAN suffer from untreated mental health disorders, although there are evidence based therapy options available. The case-management intervention study is a prospectively designed, multicenter, randomized controlled trial investigating the effect of a case-management intervention on the utilization of evidence-based treatments. The objective of the CANMANAGE consortium is to reduce the time span in which mental health disorders related to trauma remain untreated. The study will recruit 152 children and adolescents aged 4-17 years with substantiated history of CAN or witnessing parental violence who have a mental disorder that can be diagnosed and classified according to the ICD-10. Participant will be randomized to the case-management
intervention or the treatment as usual control condition in equal numbers. A case-manager is informed about possible access to health-care providers in his or her region and has received training in placing a child in an appropriate therapy program and monitor therapy outcome. Participants randomized to the control condition will receive what is currently the standard treatment for children with CAN. All participants will receive a thorough clinical assessment and reassessment when they are first recruited as well as 6, 12 and 24 months after the initial assessment. Details about the exact CAN history will be collected. The primary outcome will be the amount of children placed in evidence-based therapy (National Institute for Health and Clinical Excellence Guidelines or American Academy of Child & Adolescent Psychiatry Guidelines). Secondary outcomes are the timeframe of untreated trauma sequelae, therapy drop-out rates as well as clinical symptoms of participants.

Organizational Data

- DRKS-ID: DRKS00003979
- Date of Registration in DRKS: 2012/07/03
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): yes
- Ethics Approval/Approval of the Ethics Committee: Approved
- (leading) Ethics Committee Nr.: 122/12, Ethik-Kommission der Universität Ulm

Secondary IDs

- Universal Trial Number (UTN): U1111-1131-7917

Health condition or Problem studied

- Free text: Mental disorders due to child abuse and neglect (CAN)
- ICD10: F00-F99 - Mental and behavioural disorders
- ICD10: T74 - Maltreatment syndromes
- ICD10: X85-Y09 - Assault
- ICD10: Z59 - Problems related to housing and economic circumstances
- ICD10: Z61 - Problems related to negative life events in childhood
- ICD10: Z62 - Other problems related to upbringing
- ICD10: Z63 - Other problems related to primary support group, including family circumstances
- ICD10: Z65 - Problems related to other psychosocial circumstances

Interventions/Observational Groups
Arm 1: **Case-Management**: Allocation to a Case-Manager who is trained in acting as a broker and placing the underage CAN-child in appropriate therapy programs, to accompany the therapy process, to assist the child and its family in terms of upcoming adherence difficulties and to monitor therapy outcome.

Arm 2: **Usual Care**

### Characteristics

- **Study Type**: **Interventional**
- **Study Type Non-Interventional**: [---]*
- **Allocation**: **Randomized controlled trial**
- **Blinding**: [---]*
- **Who is blinded**: [---]*
- **Control**: **Other**
- **Purpose**: **Treatment**
- **Assignment**: **Parallel**
- **Phase**: **N/A**
- **Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels)**: **N/A**

### Primary Outcome

**Number of children with clinically relevant psychological symptoms that are receiving evidence based therapy 6 months after the implementation of the intervention**

### Secondary Outcome

1. **time period in which trauma related disorders remain untreated 6 months after intervention initiation**

2. **therapy drop-out rate 6 months after intervention initiation**

3. **posttraumatic stress symptoms 6, 12 and 24 months after intervention initiation** (assessed with UCLA PTSD-RI (University of California at Los Angeles Posttraumatic Stress Disorder Reaction Index))

4. **geneal psychopathology and behavioural problems 6, 12 and 24 months after intervention initiation** (assessment with SDQ (Strengths and Difficulties Questionnaire))

5. **quality of life 6, 12 and 24 months after intervention initiation** (assessed with KIDSCREEN-10 Index)

6. **parent mental health 6, 12 and 24 months after intervention initiation** (assessed with PDS (Posttraumatic Stress Diagnostic Scale) & PHQ-D Patient Health Questionnaire-german translation)
Countries of recruitment

- DE Germany

Locations of Recruitment

- University Medical Center Universitätsklinikum Ulm, Klinik für Kinder- und Jugendpsychiatrie/ Psychotherapie, Ulm
- Medical Center Zentrum für Psychiatrie Südwürttemberg Abteilung für Psychiatrie und Psychotherapie des Kindes- und Jugendalters, Ravensburg/Weissenau
- Medical Center Vestische Kinder- und Jugendklinik Datteln Universität Witten / Herdecke Abteilung für Kinder- und Jugendpsychiatrie/Psychotherapie, Datteln
- Medical Center Psychiatrische Klinik Lüneburg gemeinnützige GmbH Klinik für Kinder- und Jugendpsychiatrie und Psychotherapie, Lüneburg

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2012/10/29
- Target Sample Size: 152
- Monocenter/Multicenter trial: Multicenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 4 Years
- Maximum Age: 17 Years

Additional Inclusion Criteria

1. History of Child Abuse and Neglect or Witnessing Domestic Violence
2. Child now lives in a secure environment
3. Informed Consent signed by all with custody of the child and the child (if child can write)
4. Psychological disorder as can be classified by ICD-10 F

Exclusion criteria

1. Child is in evidence based therapy at the time of recruitment into the study
3. another family member is already a subject in the study

Addresses

- **Primary Sponsor**
  Universitätsklinikum Ulm
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Sources of Monetary or Material Support

- Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)

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Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2017/05/04

Trial Publications, Results and other documents

- Paper Publikation im Journal of Child Abuse and Neglect: Effectiveness of manualized case management on utilization of evidence-based treatments for children and adolescents after maltreatment: A randomized controlled trial von Helene Gertrud Ganser, Annika Münzer, Andreas Witt, Paul Lukas Plener, Rainer Muche, Rita Rosner, Maria Hagl, Lutz Goldbeck
- Paper Publikation in der Fachzeitschrift Praxis der Kinderpsychologie und Kinderpsychiatrie: Verbesserter Zugang zu evidenzbasierten Therapien für psychisch kranke Kinder und Jugendliche nach Kindesmisshandlung und -
missbrauch von Helene G. Ganser, Annika Münzer, Diana C. M. Seitz, Andreas Witt und Lutz Goldbeck

* This entry means the parameter is not applicable or has not been set.
*** This entry means that data is not displayed due to insufficient data privacy clearing.