Trial Description

Title

Behavioural, developmental, and neural effects of a standardized mother-child intervention program in adolescent mothers and their children

Trial Acronym

TeeMo

URL of the trial

http://www.teemo-aachen.de

Brief Summary in Lay Language

Children of adolescent mothers present a high-risk group for child neglect and maltreatment, especially if other stressors are present. Parenting programmes have shown to improve a range of behaviours of the teenage mothers, with enhancement of maternal sensitivity being most significant. Within a RCT design, a parental programme based on STEEP (Steps Towards Enjoyable and Effective Parenting) plus psychiatric treatment of the mother in case of mental illness will be compared to TAU (Treatment as Usual, in this case: standardized support by the child welfare office) in adolescent, high-risk mothers.
As sensitivity-focused treatments proved to be more effective than other strategies, maternal sensitivity was chosen as one of the primary outcome variables. Another primary outcome ist the Wellbeing/ child responsiveness. Secondary outcome parameters include child development and maternal affect regulation and abuse potential. Moderators of treatment outcome (e.g. genotype, child temperament of the child, neural and hormonal mechanism associated with parental bonding in the mother) as well as treatment effects in the child (cognitive and somatic development, structural brain maturation) will be systematically explored. A six-month-follow up should answer the question, wheather the interaction-focused intervention program strongly improves the wellbeing of the child, maternal sensitivity and affect regulation and thus reduces the risk for child neglect and maltreatment.
A third group of adult mothers will be explored with parallel variables and will be compared with the adolescent mothers.

Brief Summary in Scientific Language

randomized controlled study to compare adolescent mothers who get a sensitivity-focused training versus TAU as well as adult controls

Organizational Data

■

DRKS-ID: **DRKS00004409**

- Date of Registration in DRKS: **2012/09/27**
- Date of Registration in Partner Registry or other Primary Registry: **2013/01/07**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **144/12 , Ethik-Kommission an der Medizinischen Fakultät der RWTH Aachen**

Secondary IDs

- Primary Registry-ID: **ISRCTN13962271 (ISRCTN)**
- Other Secondary-ID: **01KR1207B (DLR Fördernummer)**

Health condition or Problem studied

- Free text: **adolescent mothers**
- ICD10: **T74.1 - Physical abuse**
- ICD10: **T74.0 - Neglect or abandonment**

Interventions/Observational Groups

- Arm 1: **adolescent interventiongroup: STEEP-B: 9 months of individual contact every two weeks, every second contact videointerventions, psychotherapeutic help if needed, group intervention if wanted**
- Arm 2: **adolescent Treatment as usual: welfare care of the jugendamt and the frühe Hilfen**
- Arm 3: **adult controls, no intervention or usual help by Jugendamt or frühe Hilfen**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **investigator/therapist, assessor**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **investigator/therapist, assessor**

Control: **Active control (effective treament of control group)**

Purpose: **Treatment**

Assignment: **Parallel**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

1) EAS-Scale sensitivity
2)EAS-Scales for „child's responsiveness to the parent" und „child's involvement of the parent"
Measuring times at inclusion(T1), after intervention (T2: 9 months after inclusion) and at 6-months-follow-up (T3: 15 months after inclusion).

Secondary Outcome

BIS-15 Barratt Impulsiveness Scale
BDI-II Becks Depression Inventory, Second Edition
BSDI-III Bayley Scales of Infant Development
CAARS Conners Adult ADHD Rating Scale
CAPI Child Abuse Potential Inventory (deutsche Version: EBSK)
CECA-Q Childhood Experiences of Care Abuse Questionnaire
CFT 20-R Culture Fair Intelligence Test – Scale 2, Revision
EAS Emotional Availability Scales
EAS-K kindbezogene Skala der EAS
ECR-R Experiences in Close Relationships Scale-Revised
DERS Difficulties in Emotion Regulation Scale
IBQ-R Infant Behavior Questionnaire
IPDE The International Personality Disorder Examination
IRI; EC Interpersonal Reacivity Index
M.I.N.I . Mini-International
PPP Per Protocol Population
PSI Parental Stress Index (deutsche Version: EBI)
SST Strange Situation Test (deutsch FST)
STAI State-Trait Anxiety Inventory
VASQ Vulnerable Attachment Style Questionnaire
Oxytocin, Cortisol, Östradiol, Progesteron, Genetic and epigenetic Analysis, fMRT-Paradigmen (Baby Face Incentive Delay Task as well as Infant Cry Self Distraction Paradigma)
Measuring times at inclusion(T1), after intervention (T2: 9 months after inclusion) and at 6-months-follow-up (T3: 15 months after inclusion)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Psychiatrie, Psychosomatik und Psychotherapie des Kindes- und Jugendalters, Aachen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/10/19**
- Target Sample Size: **90**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **no minimum age**
- Maximum Age: **35 Years**

Additional Inclusion Criteria

age of child 3-6 months, mother and child live together, mother caucasian, pregnancy untill 21. birthday, first or second child, verbal intervention possible (no language or intellectual problems), birth of first or second child; informed consent

Exclusion criteria

maifest substance addiction (except for nicotin), birth before end of 35th week of pregnancy, syndroms or severe illnesses within the child, severe psychiatric illnesses or suicidality within the mother, more than 3 month of seperation of mother and child, other videointervention planned

Addresses

- **Primary Sponsor**

  Klinik für Psychiatrie, Psychosomatik und Psychotherapie des Kindes- und Jugendalters

Primary Sponsor

Klinik für Psychiatrie, Psychosomatik und Psychotherapie des Kindes- und Jugendalters
Ms. Prof Beate Herpertz-Dahlmann
Neuenhofer Weg 21
52074 Aachen
Germany

Telephone: **0241-80-88737**
Fax: **0241-80-82544**
E-mail: **bherpertz-Dahlmann at ukaachen.de**
URL: **www.ukaachen.de**

■ **Contact for Scientific Queries**

Klinik für Psychiatrie, Psychosomatik und Psychotherapie des Kindes- und Jugendalters
Ms. Reinhild Schwarte
Neuenhofer Weg 21
52074 Aachen
Germany

Telephone: **0241-80-80598**
Fax: **0241-80-82544**
E-mail: **rschwarte at ukaachen.de**
URL: **www.ukaachen.de**

■ **Contact for Public Queries**

KJPPP
Ms. Julia Koslowski
Neuenhofer Weg 21
52074 Aaachen
Germany

Telephone: **0160-92906661**
Fax: **0241-80-82544**
E-mail: **jkoslowski at ukaachen.de**
URL: **www.ukaachen.de**

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.)**

Bundesministerium für Bildung und Forschung Dienstsitz Berlin
Hannoversche Straße 28-30
10115 Berlin

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

Bundesministerium für Bildung und Forschung Dienstsitz Berlin
Hannoversche Straße 28-30
10115 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.bmbf.de**

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** 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.*