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Effects of a standardized mother-child intervention programme in adolescent mothers and their children

Submission date
19/09/2012

Recruitment status
No longer recruiting

Registration date
07/01/2013

Overall study status
Completed

Last Edited
26/10/2020

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In Germany about 7,500 babies are born each year to mothers below the age of 18, and 22,000 to mothers below age 20. Teenage pregnancy in Germany is more common among individuals with lower socio-economic status and poor education. Childhood neglect, physical and sexual abuse, inconsistent parenting and being a child to a teenage mother themselves are all risk factors for pregnancy in adolescence. Thus, children of adolescent mothers are a high-risk group for child neglect and maltreatment, especially if other sources of stress are present. Their development is often disturbed and they display more aggressive behaviour than children of adult mothers. Based on the results of a previous study, a training programme for young mothers was developed (STEEP, Steps Toward Effective and Enjoyable Parenting). However, so far nothing is known about whether a child´s well-being can be increased by such a training programme. We want to find out whether STEEP helps to develop maternal sensitivity and how this effects attachment and child well-being.

Who can participate?
120 mothers who were pregnant before their 21st birthday (adolescent mothers) and their children aged 3-6 months, and 40 mothers aged 25 or over (adult mothers).

What does the study involve?
The adolescent mothers are randomly allocated to one of two groups. The intervention group will take part in a programme based on the principles of STEEP. The mothers are visited every 2 weeks by the same adviser until the child is 12 months old. Every second visit a short video of the mother and child interacting will be analyzed together with the mother, which has proven to be a promising way to increase sensitive parenting. In addition, psychiatric diseases in the mother (such as depression) will be treated by a psychiatrist/psychologist if needed. The other group will receive treatment as usual (support from the child welfare office). For further comparisons 40 mothers aged 25 or over (adult mothers) and matched for education will also be assessed. The study involves three assessment points: one at the beginning of the study, one

after 9 months of treatment and a third one after another 6 months. Participants are interviewed, complete questionnaires, and are asked to leave saliva, hair and blood samples and to undergo an MRI scan.

What are the possible benefits and risks of participating?
The STEEP intervention may improve the relationship between the mother and the child. There are no risks of participating.

Where is the study run from?
University Hospital of the Rheinisch-Westfaelische Technische Hochschule Aachen (Germany).

When is the study starting and how long is it expected to run for?
October 2012 to June 2016.

Who is funding the study?
Federal Ministry of Education and Research (Germany).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
DRKS00004409

Study information

Scientific Title

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

Acronym
TeeMo

Study objectives
Within a RCT design, a parental programme based on STEEP plus psychiatric treatment of the mother in case of mental illness will be compared to TAU (standardized support by the child welfare office) in adolescent, high-risk mothers. The primary outcome variables are the maternal sensitivity and the child's well-being. Moderators of treatment outcome (e.g. child development, genotype, child temperament, 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 control goup of adult mothers will be compared with the adolescent group.

On 04/09/2015 the overall trial end date was changed from 31/03/2014 to 30/06/2016.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Hospital of Aachen, 10/09/2012, ref: 12-006

Primary study design
Interventional

Study design
Randomised controlled trial with three arms

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Prevention of child neglect in adolescent mothers

Interventions
Three arms:
1. Adolescent intervention group
2. Adolescent treatment as usual (TAU)
3. Adult controls

The active group will take part in a programme based on the principles of STEEP when the children are at least 3 months of age. They are visited every 2 weeks by the same adviser for the duration of 9 months. The topics of the home visits will be built on the manual by Erickson /Egeland (German edition by Suess, 2009). On average mother-child dyads will receive 12-18 home visits. Every second visit a short video-documentation of mother-child interaction will be analyzed together with the mother, which has proven to be a promising tool to increase sensitive parenting. In addition, psychiatric diseases in the mother (such as depression, etc.) will be treated by a psychiatrist/psychologist if needed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Maternal sensitivity score, assessed by the sensivity-scale of the Emotional Availability Scale (EAS)
2. Child's" well-being", assessed with the EAS-Scales
3. Child's responsiveness to the parent
4. Child's involvement of the parent

There will be three appointments: first one at the beginning of the intervention right after the inclusion, next one after intervention (9 months after inclusion) and the last one 6 months after the end of intervention (15 Months after inclusion). TAU and the adult control group will be assessed with parallel appointments.

Key secondary outcome(s)
1. BIS-15 Barratt Impulsiveness Scale
2. BDI-II Becks Depression Inventory, Second Edition
3. BSDI-III Bayley Scales of Infant Development
4. CAARS Conners Adult ADHD Rating Scale
5. CAPI Child Abuse Potential Inventory (deutsche Version: EBSK)
6. CECA-Q Childhood Experiences of Care Abuse Questionnaire
7. CFT 20-R Culture Fair Intelligence Test - Scale 2, Revision
8. ECR-R Experiences in Close Relationships Scale-Revised
9. DERS Difficulties in Emotion Regulation Scale
10. IBQ-R Infant Behavior Questionnaire
11. IPDE The International Personality Disorder Examination
12. IRI; EC Interpersonal Reacivity Index
13. M.I.N.I. Mini-International Neuropsychiatric Interview
14. PSI Parental Stress Index (deutsche Version: EBI)
15. SST Strange Situation Test (deutsch FST)
16. STAI State-Trait Anxiety Inventory
17. VASQ Vulnerable Attachment Style Questionnaire
18. Analysis of fMRI-paradigms (Baby Face Incentive Delay Task and Infant Cry Self Distraction Paradigma)

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Child 3-6 months of age
2. Mother pregnant before 21st birthday
3. First or second child
4. Verbal intervention possible (no language or intellectual constraint)

5. Caucasian mother
6. Mother and child live together
7. Informed consent

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
56

Key exclusion criteria
1. Addiction (except for nicotine)
2. Birth of the child before 35th week of pregnancy was fulfilled
3. Syndromes or severe illnesses within the child
4. Severe psychiatric illness or suicidality within the mother
5. Separation of mother and child more than 3 months
6. Another video-intervention is planned

Date of first enrolment
01/10/2012

Date of final enrolment
01/11/2015

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital of the Rheinisch-Westfaelische Technische Hochschule Aachen
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Sponsor information

Organisation
Federal Ministry of Education and Research [BMBF] (Germany)

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/07/2020	26/10/2020	Yes	No
Protocol article	protocol	27/05/2015	26/10/2020	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes