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Circle of Security™ for mentally ill women with their infants

Submission date	Recruitment status	[_] Prospectively registered
04/02/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/06/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/09/2015	Mental and Behavioural Disorders	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A randomised controlled evaluation of an attachment-based group intervention program (Circle of Security™) for mentally ill women with their infants

Acronym

RCT COSI

Study objectives
Circle of Security™ (COS) intervention will lead to significantly more securely attached infants compared to treatment as usual intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical Association of Hamburg, 24/08/2009, ref: PV3269

Study design
Single-centre randomised controlled evaluation trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Maternal mental illness, attachment disorders

Interventions
COS Intervention:
The Circle of Security™ (COS) intervention was designed to alter developmental pathways of at-risk parents and their children. Conceptualised as a manualised, group-based, 20-week intervention program, the focus is on the care-giver and his relationship capacities, to enhance the quality of child-parent attachment.

Duration of treatment: 7 months

TAU:
Standard treatment practice at the mother-infant unit at the Department of Child and Adolescent Psychiatry at the University Medical Center of Hamburg.

Duration of treatment: variable duration

Timepoints of assessments:
T1: Pre-treatment
T2: Post-treatment (child's age 16 - 18 months)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Infant's attachment quality (security versus insecurity), measured at T2

Key secondary outcome(s))
1. Mother's attachment representation, measured at T1 and T2
2. Mother's interaction behaviour, measured at T1 and T2
3. Mother's reflecting functioning (RF), measured at T1 and T2
4. Mother's symptomatology, measured at T1 and T2

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Mother (no age restrictions): mental illness
2. Infant: age of 4 to 9 months at study inclusion, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Mother:
1.1. Acute crisis of mental illness (i.e. suicidal tendency)
1.2. Schizophrenia
1.3. Primary substance-abuse
1.4. Intellectual impairments (intelligence quotient [IQ] less than 80)
2. Infant:
2.1. Mental retardation
2.2. Autism

Date of first enrolment
01/01/2010

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Germany

Study participating centre
Martinistr. 52
Hamburg
Germany
20246

Sponsor information

Organisation
Hamburg Foundation for the Advancement for Research and Culture (Germany)

ROR
https://ror.org/03ec28972

Funder(s)

Funder type
Research organisation

Funder Name
Hamburg Foundation for the Advancement for Research and Culture (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/01/2014		Yes	No