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 Last Edited	Completed Condition category	Results	
		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

Contact name

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Contact details

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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 atrisk 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 adde	ed Peer reviewed	? Patient-facing?
Protocol article	protocol	30/01/2014	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/202	25 No	Yes