

Circle of Security™ for mentally ill women with their infants

Submission date 04/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 07/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 04/09/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/2010

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

Age group

Mixed

Sex

Both

Target number of participants

N = 72

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)

Sponsor details

c/o Mera GmbH

Große Bleichen 8

Hamburg

Germany

20354

Sponsor type

Research organisation

Website

<http://www.his-online.de/>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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