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Improving positive interaction between depressed mothers and their infants: an effect study on a preventive program for mother and child

Submission date
27/01/2006

Recruitment status
No longer recruiting

Registration date
27/01/2006

Overall study status
Completed

Last Edited
17/08/2009

Condition category
Mental and Behavioural Disorders

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

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
NTR457

Study information

Scientific Title

Study objectives
1. The mother baby intervention positively affects the quality of the mother-child interaction, particularly the mothers sensitivity towards her child and the childs responsiveness and involvement
2. The intervention positively affects the child's attachment security and socio-emotional functioning

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Primary study design
Interventional

Study design
Multicentre randomised single blind placebo controlled parallel group trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Depressive disorders

Interventions
Intervention: the mother-baby program comprising 8-10 home visits by an experienced prevention therapist
Control condition: 3-month parenting support comprising three telephone contacts with a child therapist
All mothers concurrently received separate treatment by a psychiatrist or psychologist for their depressive symptoms.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Quality of the mother-child interaction

Key secondary outcome(s)
Infant attachment security and socio-emotional functioning

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Mothers with an infant not older than 12 months, who met the Diagnostic and Statistical Manual of Mental Disorders fourth edition (DSM-IV) criteria for a major depressive episode or dysthymia and/or exhibited elevated levels of depressive symptoms (Beck Depression Inventory [BDI] >14). Psychiatric comorbidity was allowed.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Comorbid psychotic disorders
2. Manic depression
3. Substance abuse

Date of first enrolment
01/01/2000

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Radboud University Nijmegen
Nijmegen
Netherlands
6500 HE

Sponsor information

Organisation

University Medical Centre St. Radboud (Netherlands)

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Funder Name
Dutch Foundation for Childrens Welfare Stamps (Stichting Kinderpostzegels Nederland [SKN]) (Netherlands)

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?
Results article	results	01/05/2008		Yes	No