

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

☒ Results

☐ Individual participant data

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Multicentre randomised single blind placebo controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

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 measure

Quality of the mother-child interaction

Secondary outcome measures

Infant attachment security and socio-emotional functioning

Overall study start date

01/01/2000

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

Age group

Adult

Sex

Female

Target number of participants

71

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)

Sponsor details

Department of Clinical Psychology

P.O. Box 9104

Nijmegen

Netherlands

6500 HE

Sponsor type

Hospital/treatment centre

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

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?
Results article	results	01/05/2008		Yes	No