

# 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?
<a href="#">Results article</a>	results	01/05/2008		Yes	No