

Pilot implementation of the mother-baby intervention in the Youth Health Care

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Aim : Study the effectiveness of the intervention at the new setting. **Question:-** Is the effectiveness of the MBI the same at the Youth Health Care as at the Mental Health CareCenters as regards the outcome measurement of the sensitivity of the mother...

Ethical review	-
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON31779

Source

ToetsingOnline

Brief title

Implementation of the mother-baby intervention in the Youth Health Care

Condition

- Mood disorders and disturbances NEC
- Family issues

Synonym

Consequences of maternal depression on the development of infants or interaction problems between depressed mothers and their infants

Research involving

Human

Sponsors and support

Primary sponsor: Katholieke Universiteit Nijmegen

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Early Intervention, Infant mental health, Maternal depression, Prevention

Outcome measures

Primary outcome

Quality of the mother-child interaction: maternal sensitivity

Secondary outcome

Level of the maternal depression

Study description

Background summary

Depression is not uncommon in the Netherlands. One in five women and one in ten men have a depression at least once in their lives. Only a third of the depressions are treated at the Mental Health Care Centers (Vollebergh et al., 2003). Women are especially vulnerable to depression after the birth of a child. The prevalence of depressive disorders among mothers after giving birth is 8 to 15% (O'Hara et al., 1990). Approximately 200,000 children are born in the Netherlands every year (www.cbs.nl consulted on August 18, 2006). An average prevalence of depression of 10% means 20,000 mothers have a depression in the Netherlands every year. Depression among young mothers affects the development of young children. In the first year of their lives, children of depressed mothers exhibit behavioural, physiological and biochemical ailments (Field, 1995). At the pre-school and primary school stage, children of depressive mothers have behavioural difficulties and problems in their emotional, social and cognitive development, including their language development. In some studies, the effects on boys seem to be more serious than the effects on girls (Cicchetti et al., 1998; Murray & Cooper, 1996). Children of depressive mothers have a higher risk of developing depressive disorders themselves as children or adolescents. There is

also a risk of anxiety disorders or alcohol dependence in adolescence and young adulthood (Weissman et al., 1997).

The preventive Mother-Baby Intervention (MBI) is focused on mothers with depression and their babies.

The aim is to reduce the risks to children of depressed mothers of developmental stagnation and later psychopathology by improving the early mother-child interaction. The intervention has been developed on the basis of a transactional model focused on the early interaction between a depressed mother and her child (Van Doesum et al., 2005). In six to ten home visits, a trained social worker gives feedback on the way the mother deals with the baby, with the aim of increasing the mother's sensitivity to contact signals from the child and her cooperation and attunement to the child, adjusting depressive cognitions and promoting assertiveness. Video feedback is used as the core method in the intervention. In an RCT among seventy-one depressive mothers and their babies, the quality of the mother-baby interaction in the experimental condition (intervention group, N = 35) is compared with a control group (minimal intervention group, N = 36).

On the primary outcome measurement, a significant improvement is observed in the sensitivity of the mother six months after the end of the intervention (Emotional Availability Scales, Biringen et al., 1998).

This also holds true as regards the responsiveness of the child. In the control group, there is evidence of a worsening. The infant-mother attachment security also improves from a risk score to a score with normal values (Attachment Q-sort, Waters, 1995). The risk factors for the children of developmental stagnation and future psychopathology are thus reduced (Van Doesum et al., in press; Van Doesum et al., submitted). It has been repeatedly observed in recent years that there is an absence in the Netherlands of instruments and interventions that can be used to promote the development of young children in risk situations (Inventgroep, 2005; Programmeringsstudie Effectonderzoek JGZ (update), 2005).

The 0-4 Youth Health Care (JGZ) facilities have a wide reach (> 90%), but still do not have adequate instruments to detect risk situations and perform the kind of interventions that would provide help with

raising children (Prinsen, 2006). The Public Health Collective Prevention Act (WCPV) (2003) provides for the option of performing interventions within the made-to-measure component of the basic task package (Basistakenpakket). The MBI is performed at seventeen Mental Health Care Centers (GGZ) facilities (LSP Databank, 2005 figures). An estimated 400 mothers were reached this way in 2005. However, considering the total number of depressed parents with babies under the age of one (a minimum of 20,000), this figure is insignificant. With the MBI, mental health care facilities mainly reach mothers with a serious depression at a late stage. The disturbed mother-child interaction has thus been going on for quite some time and is more difficult to correct. A broader application of the intervention at the Youth Health Care facilities, where virtually all mothers come with their babies for prenatal and postnatal care, can considerably increase the number of mothers and babies who can be reached at an early stage. Implementing the intervention among depressive mothers requires specific expertise.

Study objective

Aim : Study the effectiveness of the intervention at the new setting.

Question:

- Is the effectiveness of the MBI the same at the Youth Health Care as at the Mental Health Care Centers as regards the outcome measurement of the sensitivity of the mother to contact signals from the child?

Study design

The effects of the intervention on the mothers and babies are measured via one pre-test measurement and two post-test measurements (T0 at the start of the intervention, T1 at the last session of the intervention and T2 six months after the completion of the intervention). The same research instruments are used as in the previous effect study. The effect of the Mother-Baby Intervention is stipulated on the variable quality of the mother-child interaction. The maternal sensitivity is the main outcome measure.

For this purpose, use is made of the video recordings of the mother-child interactions in all three of the measurements. The recordings are scored by a minimum of three trained observers based on the Emotional Availability Scales (EAS, Biringen et al., 1998). These scales measure the quality of the interaction: the maternal sensitivity and the responsiveness and involvement of the child. Background information on the mother and child are collected during the three measurements using a composite questionnaire. The level of the mother's depressive symptoms is measured using the Beck Depression Inventory (BDI, Beck et al., 1988). The effect outcomes of the participants in the pilot implementation are compared with the results of the previous effect study (control and experimental group, $N = 36$ and $N = 35$ respectively). Power calculation: In order to define a standardized effect size of d that is larger than or equal to 0.33 (medium-sized clinical effect) as significant in the statistics with an $\alpha = 0.05$ (one-sided) and power $(1 - \beta) = 0.80$, it is necessary to have forty-two individuals for each condition. With an anticipated drop-out of 15% at the most (based on prior research), we can conclude that a sample of sixty is more than enough.

Intervention

The mother-baby intervention comprises a total of 8 to 10 home visits. A home visitor (qualified health nurse) visits the depressed mother and her infant at home, where he or she records the mother-child interaction on videotape. A multi-disciplinary team consisting of specialists in infant mental health care who are associated with the home visitor's centre subsequently analyze the videotape, focusing in particular on the mother's sensitivity to her infant's signals and needs. Based on their analysis of the taped interactions, the home-visitor then chooses the strategies best suited to achieve these goals and fine-tunes the intervention to the mother's needs. Based on the video observations and the outcome of the discussion with the parents, the mother is encouraged to expand her range of appropriate communicative behaviours, and is shown when to respond to the baby's eye-contact, movements or sounds. The father, when present, is encouraged to support his wife in her interactions with the child. In addition to the video observations, one or more of the following techniques are used, depending on the needs of the parents: modelling, cognitive restructuring, baby massage and practical pedagogical support.

Study burden and risks

No risk

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Mothers with an elevated level of depression symptoms and infants in the age between 3-12 months. Mothers with a score of 15 or higher on the Beck Depression Inventory will be included.

Exclusion criteria

Mothers who are not able to read and write in Dutch

Mothers with other psychiatric disorders

Infants with physical or mental health problems

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 06-01-2009

Enrollment: 66

Type: Actual

Ethics review

Approved WMO

Date: 19-11-2008

Application type: Amendment

Review commission: METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL20207.028.07