The effectiveness of screening for postpartum depression in child health care

Submission date	Recruitment status	Prospectively registered
28/10/2016	No longer recruiting	[_] Protocol
Registration date	Overall study status	Statistical analysis plan
09/11/2016	Completed	[] Results
Last Edited	Condition category	Individual participant data
09/11/2016	Mental and Behavioural Disorders	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Although a depression in the period after giving birth (a postpartum depression) is not a rare condition, many cases go unnoticed. Many women do not recognize the symptoms of postpartum depression (PPD) and fail to seek help and health care professionals who see the mother often do not spot the signs either. When PPD is not identified, this can have a serious impact on the functioning of the mother, the mother-child relationship, the mother's ability to care for their baby and on the family as a whole. One way to better identify PPD in an early stage is by screening women for signs of depression using a questionnaire. There are well developed screening instruments for PPD, including the Edinburg Postnatal Depression Scale (EPDS). In the Netherlands almost all mothers (around 95%) of newborn children visit the Child Health Care Centre (CHC) routinely during the first year after giving birth. Incorporating PPD screening into these visits could therefore provide a unique opportunity to improve the detection and treatment of PPD. The aim of this study is to find out whether screening by CHC with the EPDS is a good way of identifying women with PPD and speeding up the recovery of those with PPD.

Who can participate?

All mothers of children born between the first of December 2012 and the 31st of March 2014, using the offer of Child Health Care in the regions of the participating organizations.

What does the study involve?

Mothers in the screening region are asked to complete the a questionnaire about depression before their planned visit to the CHC center at one, three and six months. The physician discusses the outcome with the mother during the visit. Depending on the score, the mother is referred for further help or treatment or an extra home visit by the CHC nurse. In the control region the mothers and their infants also visit the CHC at one, three and six months, but without completing a depression questionnaire. The physician may ask the mother about depressive symptoms and give advice for further help, but this is not a required part of the consultation. The number of mothers suffering from depression after nine months is then measured.

What are the possible benefits and risks of participating? There are no direct benefits or risks involved with participating in this study. Where is the study run from?

Mothers in the screening region attend CHC centres in the region of Twente (GGD Twente), mothers for the control regioon attend CHC centres in the regions of Apeldoorn (Vérian) and Deventer (GGD IJsselland) (Netherlands)

When is the study starting and how long is it expected to run for? October 2011 to March 2014

Who is funding the study? Netherlands Organization for Health Research and Development (ZonMw) (Netherlands)

Who is the main contact? Dr Angarath van der Zee – van den Berg a.i.vandenberg@utwente.nl Dr Magda Boere-Boonekamp m.m.boere-boonekamp@utwente.nl

Study website http://www.post-up.info/

Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

AWJT project 15901.0003 (ZonMw)

Study information

Scientific Title

The Effectiveness of Screening for Postpartum Depression in Child Health Care: does Screening Improve Maternal Mental Health and the Child's Socioemotional Development when Compared to Care as Usual?

Acronym

Post-Up study

Study objectives

Screening for postpartum depression (PPD) by Child Health Care improves the early detection and results in a more rapid mental recovery of the mothers identified with PPD, better quality of parenting, and less problems in social-emotional development of the children of these mothers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The protocol for the study was submitted to the Medical Ethics Committee Twente (MECT) for adjudication. The METC exempted the study from review as the nature of the study was found beyond the remit of the Medical Sciences Research with Human Subjects Act (Wet medischwetenschappelijk onderzoek met mensen) and the measures pertaining to confidentiality and informed consent were found appropriate.

Study design

Prospective non-randomised study

Primary study design Interventional

Secondary study design

Non randomised study

Study setting(s) Other

Study type(s) Screening

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet in Dutch

Health condition(s) or problem(s) studied

Postpartum depression

Interventions

Participating mothers will be asked to fill in the 10-item EPDS questionnaire prior to their planned visit to the Child Health Care (CHC) center at 1, 3 and 6 months. The CHC physician scores the EPDS during the visit and discusses the outcome with the mother. A score \geq 13 is interpreted as a high risk to be diagnosed with major depression. If the clinical impression of the WBC physician corresponds to the score, the mother will be advised to consult a family practitioner or mental health professional. In the case of EPDS scores from 9 to 12, the mother is offered a home visit by the CHC nurse. In all cases, the decision on the follow up step after screening is in dialogue with the mother.

In the control region the mothers and their infants visit the CHC at 1, 3 and 6 months. At these visits, the physician has the usual conversation with the mother and can ask about their psychological well-being if they want (this is not a standardized part of the consultation). If post-partum depression is suspected, the mother can be offered a home visit or referred for further help as per standard practice.

Intervention Type

Other

Primary outcome measure

Presence of depression (major and minor) at 9 months postpartum, instrument: Dutch translation of the depression subscale of the Mini International Neuropsychiatric Interview at 9 months postpartum.

Secondary outcome measures

Mother:

1. Health-related quality of life is measured using the Short-Form 12-Item Health Survey (SF-12) at 12 months postpartum

2. Maternal anxiety is measured using the 6-item short form of the state scale of the Spielberger State-Trait Anxiety Inventory (STAI) at 12 months postpartum

3. Quality of parenting is measured using the Dutch translation of the Maternal Self-Efficacy in the nurturing role questionnaire (SENR) at 12 months postpartum

Child:

Socioemotional development is measured using Ages and Stages Questionnaires: Social Emotional (ASQ:SE), 12 months version, at 12 months postpartum.

Cost-effectiveness:

1. Health care use of the mother is measured using self-report questions at 12 months postpartum

Health care use of the infant is measured using self-report questions at 12 months postpartum
Proportion of mothers who receive treatment for postpartum depression is measured using self-report questions at 12 months postpartum

4. Sick leave of the mother is measured using self-report questions at 12 months postpartum

Overall study start date

01/10/2011

Completion date 30/11/2016

Eligibility

Key inclusion criteria

All mothers of children born between the first of December 2012 and the 31st of March 2014
Visiting Child Health Care (CHC) centers in the eastern part of the Netherlands

Participant type(s) Patient

Age group

Adult

Sex

Female

Target number of participants

To demonstrate the expected effect of the intervantion with a significance level of 5% and a power of 80%, the sample size had to be 1545 women for both groups.

Key exclusion criteria

1. Insufficient mastery of the Dutch language to fill out questionnaires

2. Not utilizing the offer of Well Baby Care

3. First contact with Well Baby Care after the child was 3 months of age

Date of first enrolment

01/12/2012

Date of final enrolment 31/03/2014

Locations

Countries of recruitment Netherlands

Study participating centre GGD Regio Twente Nijverheidstraat 30 Enschede Netherlands 7511JM

Study participating centre Vérian Postbus 1032 Apeldoorn Netherlands 7301 BG

Study participating centre GGD IJsselland Schurenstraat 8a Deventer Netherlands 7413 RA

Sponsor information

Organisation University of Twente - Institute for Innovation and Governance Studies

Sponsor details

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Sponsor type University/education

Website www.utwente.nl/igs ROR https://ror.org/006hf6230

Funder(s)

Funder type Not defined

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

Results and Publications

Publication and dissemination plan

Planned submission of at least two publications in a high-impact peer reviewed journal between December 2016 and July 2017.

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date