Healthy Pregnancy 4 All -2: Maternity care

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29568

Source
Nationaal Trial Register

Brief title
Healthy Pregnancy 4 All-2 (HP4All) study.

Health condition

Pregnancy, patient tailored care, maternity care, antenatal care, maternal empowerment

Sponsors and support

Primary sponsor: The research team has received funding from the Ministry of Health, Welfare and Sports in order to execute the Healthy Pregnancy 4 All study. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of a manuscript.
Source(s) of monetary or material Support: The research team has received funding from the Ministry of Health, Welfare and Sports in order to execute the Healthy Pregnancy 4 All study. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of a manuscript.

Intervention

Outcome measures

Primary outcome

The primary outcome is the mean overall maternal empowerment score (range 1-4), assessed using the Maternal Empowerment Questionnaire (MEQ) between day 7 and 14 postpartum.

Secondary outcome

Secondary outcomes are: maternal physical health assessed by The Short Form Health Survey (SF-36) between day seven and 14 postpartum, the Edinburgh Postnatal Depression Scale (EPDS) assessed six to 12 weeks postpartum, the initiation of breastfeeding (no/yes), the prolongation of breastfeeding (categorical: continued, added formula feeding, stopped) measured at two separate time point; first between day seven to 14 postpartum, and second between six to twelve weeks postpartum, parental compliance with neonatal vitamin-K supplementation when breastfeeding (no/yes), parental compliance with neonatal safe sleep practices (no/yes), maternal smoking behaviour postpartum (no/yes), maternal alcohol use postpartum (no/yes), and additional maternal and neonatal health care utilization in the first three months postpartum (no/yes) assessed between six to 12 weeks postpartum.
In addition, we will assess implementation of our study protocol via questionnaires addressed to managers of maternity care organisations and to local researchers.

Study description

Background summary

This study uses a cluster randomized controlled trial design in six municipalities in the Netherlands, including 12 maternity care organisations at 15 different locations throughout the country. In each municipality, both an intervention, and a control cluster are formed. The intervention under study is a systematic risk assessment for medical and non-medical risk factors during pregnancy in conjunction with client-tailored care during pregnancy and the postpartum period. The primary outcome is maternal empowerment measured between day six and 14 postpartum. The results from this trial will provide evidence on whether structured risk assessments in conjunction with patient-tailored care for high-risk pregnant women by maternity care providers is feasible in terms of effectiveness and implementation.

Study objective

The results from this trial will provide evidence on whether structured risk assessments and customized maternity care for high-risk pregnant women by maternity care providers is feasible in terms of effectiveness, especially regarding maternal empowerment.

Study design

Risk-assessment during pregnancy (between 28-37 weeks of pregnancy). Follow questionnaires postpartum; firstly 7-14 days postpartum, and secondly 6-12 weeks postpartum.

Intervention

The study is embedded in the Healthy Pregnancy 4 All- 2 program (HP4All-2), a nationwide program in the Netherlands that aims to reduce health inequalities and improve the care for young children and their mothers.

Within the intervention clusters, participants will receive a structured risk assessment during pregnancy. The risk assessment focuses on medical and non-medical risk factors. The consequent content of the intervention is informed by these outcomes with proactive, client-tailored care during pregnancy, labour, and the postpartum period. The risk assessment is based on the Mind2Care (M2C); a Dutch screen-and-advice tool developed and validated for routine us in antenatal obstetric care, complemented with an adjusted form of the Maternal Empowerment Questionnaire (MEQ).

The personalised care pathways are based on standard care pathways within each participating organisation and within the participating municipality. Participants in the control clusters will receive the same risk assessment. This assessment will however be followed by conventional maternity care during pregnancy, labour, and the postpartum period.

The local researcher, a trained maternity care professional or assistant, will be the contact between the study-team and the participants. All local researchers involved in interviewing participants will be educated extensively to use the risk assessment and to guide the participants in answering the questions within the risk assessment. This education exists of two sessions of three hours and will be guided by a well-established Dutch educational agency together with the principal investigator of the research team. In-service training consists of the risk factors that will be evaluated using the risk assessment tool, the association between risk factors and adverse health outcomes, the possible tailored care towards women’s circumstances and needs, and strengthening women’s capabilities. It further contains group exercises in communication and respect, in order to correctly include participants in a research project and to answer questions of participants in an proper way.

Contacts

Public
PO Box 2040
J Lagendijk
Department of Obstetrics and Gynaecology, Erasmus MC, University Medical Centre

Rotterdam 3000CA
The Netherlands
Scientific
PO Box 2040
J Lagendijk
Department of Obstetrics and Gynaecology, Erasmus MC, University Medical Centre

Rotterdam 3000CA
The Netherlands

Eligibility criteria

Inclusion criteria

Support for the study in a maternity care organisation was sought from senior staff, and executives with responsibility for clinical quality and safety. Maternity care organisations were required to demonstrate sufficient capacity to maximise their engagement with the study. The studied intervention requires an interview scheduled at home for each client. All pregnant women cared for by participating maternity care organisations, which have a scheduled home visit during pregnancy, within the selected postal codes of the participating municipalities, are invited to take part in the trial.

Exclusion criteria

Exclusion criteria are not having a planned home visit during pregnancy and inadequate knowledge of the Dutch language, English language, Polish language, or Turkish language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	15-08-2015
Enrollment:	1711

Type:	Unknown

Ethics review

Positive opinion

Date:	27-03-2017
Application type:	First submission

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
NTR-new	NL6164
NTR-old	NTR6311
Other	MEC : 2015-156

Study results