Providing an optimal start for vulnerable mother and child dyads during the early postpartum period.

No registrations found.

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

Summary

ID

NL-OMON22820

Source
Nationaal Trial Register

Brief title
TBA

Health condition

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

Sponsors and support

Primary sponsor: ZonMw (the Netherlands Organisation for Health Research and Development). The funders have no role in study design, data collection and analysis, decision to publish, or preparation of manuscripts
Source(s) of monetary or material Support: ZonMw (the Netherlands Organisation for Health Research and Development). The funders have no role in study design, data collection and analysis, decision to publish, or preparation of manuscripts

Intervention

Outcome measures

Primary outcome

Primary outcome
The primary outcome is the prevalence of low maternal empowerment postpartum and will be assessed via the Maternity Empowerment Questionnaire (MEQ) during pregnancy and postpartum. The MEQ consists of five domains: (1) Looking after yourself, (2) My baby, (3) My family, (4) The future, and (5) Maternity care. The fifth domain “Maternity care” will not be considered for the maternal empowerment, since it directly assesses the extent to which maternity care has contributed to the participants’ empowerment. The first three domains are part of the structured risk assessment during pregnancy. The full MEQ is assed at the fifth day postpartum and six weeks postpartum. Maternal empowerment is defined as the median score across the first four domains within the MEQ.
Low maternal empowerment is defined as a score beneath the 20th centile of all empowerment scores within the control arm.
the MEQ is assessed at the first week postpartum and 6 weeks postpartum.

Secondary outcome

• Maternal health related quality of life (PROMIS-10)
• Maternal (postpartum) depression (EPDS)
• Maternal confidence in breastfeeding (BSES-SF) along with success rates
• Maternal satisfaction with the provided care (two short questionnaires “shared decision making” and “confidence in care providers”, developed by ICHOM in the Pregnancy & Childbirth Standard Set) [ref]
• Lifestyle factors such as maternal smoking, alcohol consumption, and drug use
• Feasibility of the eHealth application (usage of the application, user experience among participants and MCOs)

Study description

Background summary

Rationale: The postpartum period is an important period for preventive strategies as common maternal and child health problems may become apparent. Women with a lower socioeconomic status tend to have lower maternal empowerment, increasing their risks of adverse maternal and child health outcomes. Underserved women (i.e. with regard to the amount of maternity care uptake postpartum) more often have a low socioeconomic status and as such missed opportunities for enhancing maternal and child health care postpartum occur in routine practice.
Current clinical guidelines for maternity care assistants (MCAs), their educational background and their in-house training sessions insufficiently acknowledge the relevance of non-medical risk factors, including those associated with low socioeconomic status, in relation to adverse

maternal and child health outcomes postpartum. Moreover, the National Indication Protocol that indicates the amount of postpartum care mostly addresses medical issues.
To provide an optimal start after childbirth, maternity care assistants, together with community midwives and obstetricians, need to better identify vulnerable women early in pregnancy and tailor the amount and content of care to be provided with emphasis on preventive strategies.
Promising results have been obtained when an m-health tool is used for personal lifestyle and medical health care support, also during pregnancy. To reach successful enrolment of an m-health tool in a vulnerable population, only providing an m-health tool is not enough. Implementation of an m-health approach (i.e. text messages and information provision) by maternity care assistants, that provides identification of vulnerable women and guidelines for maternal-focussed tailored care from pregnancy onwards, might be promising for maternity care assistants to tailor their care provision from pregnancy onwards and hereby provide an optimal start after childbirth.
Based on the intensive and preventive structure of maternity care along with the opportunities for maternity care assistants to tailor care from pregnancy onwards we hypothesize that a window of opportunity can be established with a supportive m-health service intervention that aims to enhance maternal empowerment postpartum.

Objective: In this study, we aim to evaluate the effectiveness of an intervention that enhances maternal empowerment in the postpartum period by the combination of 1) timely identification of vulnerable women (i.e. during the first or early second trimester of pregnancy) and 2) maternal-focused tailored care during pregnancy and the postpartum period supported by an m-health tool introduced by maternity care assistants.

Study design: A randomised controlled trial will be conducted along with participating maternity care organisations (MCOs)

Study objective

Reduced amount of low empowerment scores postpartum among the intervention group, achieved by an eHealth application to support vulnerable mother and child dyads.

Study design

Risk-assessment during pregnancy (25 weeks of gestation). Follow questionnaires 34 weeks of gestation, postpartum: first week postpartum (+/- 5 days postpartum) and 4-6 weeks postpartum.

Intervention

eHealth application with reliable information, supporting text messages and questionnaires.
Structured risk screening at 25 weeks of gestations by MCOs.
Risk-guided tailored care during pregnancy and postpartum period

Contacts

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Eligibility criteria

Inclusion criteria

A pregnant woman is eligible if she is vulnerable (patient is assessed on her vulnerability during subscription to one of the participating MCOs). Vulnerability is defined as 3 or more problems during pregnancy.

Exclusion criteria

• gestational age above 25 weeks;
• under-aged women: under the age of 16 years;
• having a smart phone that is not compatible with the eHealth application: without Android or iOS operating system;
• insufficient command of the Dutch language: that text can be read and understood;
• unwillingness to sign a digital informed consent form in the eHealth application.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2019
Enrollment:	494
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/a

Ethics review

Positive opinion

Date:	10-09-2019
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	NL8014

Register	ID
Other	METC Erasmus MC : MEC-2018-1455

Study results

Summary results
N/a