Improving Care of Pregnant Women in the Netherlands by early identification of Perinatal & Maternal Risks Pregnancy Risk Flagging System Phase 2: satisfaction

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To assess patient satisfaction of antenatal care perceived by (vulnerable) pregnant women and explore the user experience by (vulnerable) pregnant women and HCPs (healthcare professionals working in antenatal care) while using the app for real time...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Maternal complications of pregnancy
Study type	Observational non invasive

Summary

ID

NL-OMON51019

Source
ToetsingOnline

Brief title
Pregnancy Risk Flagging System phase 2

Condition

- Maternal complications of pregnancy

Synonym
(Vulnerable) pregnancy

Research involving
Human

Sponsors and support

Primary sponsor: Philips Electronics Nederland B.V.
Source(s) of monetary or material Support: Ministerie van OC&W,Topsector Kennis en Innovatie High Tech Systems Materials (TKI HTSM)

Intervention

Keyword: Pregnancy, Remote Patient Monitoring, Risk flagging, Vulnerability

Outcome measures

Primary outcome

The primary outcome is a comparison of patient satisfaction between the intervention and control group, measured at 18-22 weeks of gestation (baseline) and at 35-37 weeks of gestation using the Pregnancy and Childbirth Questionnaire (PCQ).

Secondary outcome

Secondary parameters include an exploration of the usability and user experience, measured by means of customized quantitative and qualitative questions as well as the System Usability Scale (SUS), for the pregnant women in the intervention group at 28-29 and 35-37 weeks of gestation and for HCPs using the basic dashboard to be sent out 4 months after the start of the study and at the end of the study.

In addition, a retrospective analysis of the PRFS risk flagging functionality will be conducted.

Finally, an analysis on satisfaction and user experience for a subgroup of vulnerable women (retrospectively identified by using the R4U questionnaire) versus not-vulnerable women will be performed. This will also be done for the women in primary care only, in secondary care only and referred during

pregnancy.

Study description

Background summary

Pregnant women seem to find it hard to distinguish physiological changes during pregnancy from pathological symptoms indicating a potential pregnancy complication. Early detection of a pregnancy complication may prevent or decrease the risk of adverse maternal and neonatal outcomes. Vulnerable women are particularly at risk of adverse outcomes during the perinatal period due to multiple factors. There is a need to provide pregnant women with reliable information and advice regarding physiological and pathological symptoms and when to contact a healthcare professional (HCP).

We have developed a prototype for real time patient monitoring of pregnant women, as RPM (remote patient monitoring) is still lacking in the area of antenatal care. The Pregnancy Risk Flagging System (PRFS) consists of a mobile application (app) called for pregnant women to self-report symptoms and parameters as blood pressure and foetal kick count.

Leveraging this technology for antenatal care could contribute to higher patient satisfaction by enabling increased personal care and by assisting earlier identification of potential pregnancy risks which may occur between ANC visits, because of real time monitoring. This, in turn, could have the potential to improve maternal and neonatal outcomes. Specifically, vulnerable pregnant women could benefit from this technology as they make suboptimal use of the current healthcare system. However, in order to implement this system in daily practice, user experience and risk flagging functionality must be examined first.

Study objective

To assess patient satisfaction of antenatal care perceived by (vulnerable) pregnant women and explore the user experience by (vulnerable) pregnant women and HCPs (healthcare professionals working in antenatal care) while using the app for real time symptom reporting, in addition to regular antenatal care. Furthermore, the risk flagging functionality of this system will be examined retrospectively.

Study design

Multicenter, randomized controlled trial.

Intervention

Use of app by pregnant women to report their pregnancy symptoms in addition to the regular antenatal care. During the antenatal care visit (ANC visit), the HCP has access to a symptoms-overview of the pregnant woman in the PRFS basic dashboard prototype and this will be discussed between the pregnant woman and HCP. The control group of pregnant women will use regular antenatal care.

Study burden and risks

The PRFS will not interfere with regular antenatal care, since the risk flagging will be done asynchronous. Hence the study yields low risk for the pregnant woman, foetus or HCP. Pregnant women need to make time to report their symptoms in the app and to fill in the questionnaires.
HCPs need to make time to discuss pregnant woman*s reported symptoms with them during ANC visits and to fill in the questionnaires.

HCPs and pregnant women of the intervention group may benefit from improved communication and more personalised care. Furthermore, the PRFS is a promising tool in addition to regular antenatal care. It may improve the experience of antenatal care for (vulnerable) pregnant women and HCPs and, in the future, it may improve earlier detection of pregnancy risks than a scheduled ANC visit, thus contributing to the prevention or early treatment of complications.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

· Pregnant women with a viable pregnancy
· 18 years or older
· Able to read and understand English and/or Dutch language
· Have smartphone and internet access
o iPhone: at least iPhone 7, running the latest iOS version that is on the market at the date of
starting the study
o Android: not older than 5 years old phone running at least Android 6.0
· Willing and able to provide informed consent
· Woman expects to be available during entire study follow-up (meaning, she has no plans to travel or move in near future during her pregnancy)

Exclusion criteria

· Anomalous findings of foetus at the 20 weeks ultrasound scan

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	15-03-2021
Enrollment:	164
Type:	Actual

Ethics review

Approved WMO Date:	22-12-2020
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	23-02-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	12-04-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	13-12-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	24-05-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL75365.015.20
Other	NTR NL8872