Pregnancy Risk Flagging System Phase 2: satisfaction

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We hypothesize that the pregnant women in the intervention group (using the PRFS) will be more satisfied about the perceived quality of antenatal care than the women in the control group.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20682

Bron
Nationaal Trial Register

Verkorte titel
PRFS

Aandoening

not applicable

Ondersteuning

Primaire sponsor: Philips Experience Design
Overige ondersteuning: eMTIC strategic partnership

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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 perinatal 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 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.

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.

Population: 164 pregnant women recruited at 18-22 weeks of pregnancy (after the 20 weeks ultrasound scan until 6 weeks postpartum. Pregnant women will be recruited from 3 sites in The Netherlands to achieve sample size: one hospital (Máxima Medical Center Veldhoven, and two primary care midwifery practices: PUUR Verloskundig Centrum Veldhoven and 040 Verloskunde, Eindhoven.

Intervention: Use of app to report their pregnancy symptoms in addition to the regular antenatal care by pregnant women. 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.

Main study parameters: 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 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 risk flagging functionality by the PRFS will be conducted.
Finally, a 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.

Doel van het onderzoek

We hypothesize that the pregnant women in the intervention group (using the PRFS) will be more satisfied about the perceived quality of antenatal care than the women in the control group.

Onderzoeksopzet

Expected start date half of November after ICBE/METC approval
Expected end date: 9 to 12 months after start date

Onderzoeksproduct en/of interventie

Use of app to report their pregnancy symptoms in addition to the regular antenatal care by pregnant women. 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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Pregnant women with a viable and non-anomalous foetus at the 20 weeks anomaly scan
• 18 years or older
• Able to read and understand English and/or Dutch language (we are aware this could lead to selection bias but in this phase of the experiment, questionnaires will only be available in English and Dutch)
• Have smartphone and internet access
iPhone: at least iPhone 7, running the latest iOS version that is on the market at the date of starting the study
Android: not older than 5 years old phone running at least Android 6.0
• Willing and able to provide informed consent (IC)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Anomalous foetus at the 20 weeks ultrasound
• In case the pregnant woman continues her ANC visits before 35-37 weeks of gestation in another hospital other than Máxima MC or another midwifery practice other than PUUR or 040 Verloskunde (because HCPs at other centres do not have access to the PRFS dashboard prototype, and the pregnant women did not receive the PCQ and SUS questionnaires at that time yet)
• Delivery before the second questionnaire measurement at 35-37 weeks of gestation
• Perinatal death

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-11-2020
Aantal proefpersonen:	164
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8872
Ander register	METC Máxima MC, ICBE Philips : METC W20.115

Resultaten