DIGITAL HEALTH IN OBSTETRIC CARE

Hans van den Heuvel

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CHAPTER 1
INTRODUCTION

PREGNANCY AND CHILDBIRTH CARE IN THE NETHERLANDS

In the Netherlands approximately 170.000 children are born annually.[1] The majority of these children is born healthy. However, around 14% of babies do not have the best possible start of life.[2,3] Amongst others, the increase of unhealthy life style, obesity, and advanced maternal age result in an increase of complications in pregnancy. These predisposing factors may lead to hypertension, fetal growth restriction, (gestational) diabetes or preterm birth. Furthermore, complications in pregnancy are known to subsequently affect long term maternal health as well as health of the offspring.[4] To diagnose and monitor pregnancy complications, frequent surveillance of both maternal and fetal condition is recommended. Antenatal care for such high-risk pregnancies in The Netherlands is concentrated in secondary and tertiary care hospitals, after referral from primary care midwifes.

Around 10% of women develop a hypertensive disorder of pregnancy, such as preeclampsia. The International Society for the Study of Hypertension in Pregnancy has recently published their latest classification and discerns chronic hypertension (hypertension diagnosed <20 weeks of gestation), gestational hypertension (arising de novo after 20 weeks of gestation) and preeclampsia (gestational hypertension, combined with one or more of the following: proteinuria, uteroplacental dysfunction, or other signs of maternal organ dysfunction), see Table 1.[5] Hypertension in pregnancy is associated with maternal risks such as preeclampsia, severe hypertension, organ failure, seizures, stroke and mortality. Perinatal complications of hypertensive disorders of pregnancy include fetal growth restriction, perinatal asphyxia, placental abruption, preterm delivery, and subsequent neonatal respiratory distress and admission to intensive care.

Risk factors for the development of preeclampsia in pregnancy include prior preeclampsia, chronic hypertension, pregestational diabetes mellitus, obesity (BMI>30), and assisted reproduction.[5] For pregnant women at higher risk of complications, the frequency of antenatal visits may vary from 2 weeks up to 3 times a week.[6] Especially those with uncontrolled hypertension or antihypertensive medication use will visit the hospital more frequently. During these visits focus is on maternal parameters as blood pressure, symptoms, weight, and urine or blood analysis. The fetal condition can be evaluated using ultrasound assessment of growth, Doppler velocity of uterine-placental flow, fetal movements and cardiotocography. The latter is used to determine fetal heart rate patterns and its variability.

These recurrent visits for risk assessment, either planned or unplanned, interfere with daily life and can be burdensome for the pregnant patient and her support system. Due to the distance from home to hospital, these visits result in more travel time and parking costs compared to primary care visits. Additionally, antenatal visits may lead to considerable work absence of both women and partners. Furthermore, pregnancy complications can cause stress and anxiety.

Hypertension known before pregnancy or present in the first 20 weeks	
Chronic hypertension	hypertension predating the pregnancy or <20 weeks' gestation
White-coat hypertension	elevated office/clinic (≥140/90 mmHg) blood pressure, but normal when measured at home or work (<135/85 mmHg); it is not an entirely benign condition and conveys an increased risk for preeclampsia.
Masked hypertension	characterized by BP that is normal at a clinic or office visit but elevated at other times, most typically diagnosed by 24-hour ambulatory BP monitoring (ABPM) or automated home BP monitoring.
Hypertension arising de novo at or after 20 weeks	
Gestational hypertension	new onset of hypertension (BP ≥140 mmHg systolic or ≥90 mmHg diastolic) at or after 20 weeks' gestation in the absence of features of preeclampsia.
Preeclampsia De novo; or Superimposed on chronic hypertension	Gestational hypertension accompanied by ≥1 of the following new-onset conditions at or after 20 weeks' gestation: - Proteinuria - Other maternal organ dysfunction, including: o Acute kidney injury (creatinine ≥90umol/L) o Liver involvement (elevated transaminases) with or without right upper quadrant or epigastric abdominal pain o Neurological complications (examples: eclampsia, stroke, clonus, severe headaches, and persistent visual scotomata) o Hematological complications (thrombocytopenia, disseminated intravascular coagulation, hemolysis) o Uteroplacental dysfunction (such as fetal growth restriction, abnormal umbilical artery Doppler wave form analysis, or stillbirth)

Table 1. Classification of hypertensive disorders of pregnancy. (BP: blood pressure)
Adapted from the International Society for the Study of Hypertension in Pregnancy (ISSHP) [5]

For most of these women at risk of complications in pregnancy, care can be provided in the outpatient department. However, from the point complications are diagnosed, hospital admission is recommended for close antenatal surveillance. During this admission, maternal and fetal symptoms and signs can be followed on a daily basis. Results from an inventory by the Dutch Healthcare Authority (NZa), Dutch Society for Obstetrics and Gynaecology (NVOG) and Perined (The Dutch Perinatal Registry) estimate that yearly, around 20.000 women are admitted in pregnancy for antenatal complications. This accounts for 12% of pregnancies in the Netherlands and these numbers are similar in other high-income countries.[6-8] Hospitalisation during pregnancy is considered an event of significant impact, because of combined stressors of the admission and (complicated) pregnancy.[9-11] It has a negative impact on well-being of both women and fetus. Symptoms of increased psychological stress, lack of activity, feelings of uncertainty and separation of home and family account for dissatisfaction of the in-hospital stay amongst women.

Besides consequences for patients faced with complications during pregnancy, increased clinic visits and hospital admission also pose a burden for health care resources. Health care services are challenged by shortage of professional staff.[12] As the cost of healthcare continues to rise, policies for cost reduction without concessions to the quality of care are required for a sustainable health care system.

EMERGENCE OF DIGITAL HEALTHCARE

In search for improvement of care for women with complicated pregnancies, answers may be found in the emergence of digital health. Digital health, or eHealth, is an umbrella term for health care practice supported by electronic processes and communication.[13] Following the definition of Eysenbach, eHealth is not only a technical development, but more likely an emerging field at the intersection of medical informatics, public health and business. Moreover, he mentions that its definition should be interpret with caution as eHealth is a dynamic field, which is constantly changing.[14]

Access to mobile communication is increasing globally, with an estimated 75% of the world population now connected through mobile phone connectivity. Over 2,000 health-related smartphone applications specific for obstetrics and gynaecology can be found in the Apple iTunes store.[15] In recent years, research focusses on technological advancements to support both patients as well as health care providers. As a result of these technologies, the potential of health care with use of telemedicine is now facilitating management of patient's problems from home.

Multiple types of telemedicine can be defined with regards to complexity. In this thesis, we use the terms home monitoring, self-monitoring and telemonitoring in the context of obstetric care, and defined them as follows:

Home monitoring is a type of domiciliary care for pregnant women with help of hospital personnel travelling to a patient's home. During this home visit, a nurse or midwife may perform physical examination, measure blood pressure, fetal heart rate, and uterine contractions and draw blood or test urine. Measurements of cardiotocography and notes on current condition are sent to the electronic patient record with use of Internet connection.

Self monitoring is the term used for self-measurements of vital parameters like blood pressure or maternal glucose. Values are written down by the patients in a diary or more contemporary in a smartphone app. Patients are instructed what to do when certain thresholds are being crossed, for example contact their health care provider or present to the hospital.

Telemonitoring is a more advanced type of monitoring with self-recorded physiologic data and/or symptom scores transferred from the patients' home to the health care professional with help of telephone or internet connection. After reviewing the uploaded data in the clinic, the health care professional can decide to contact the patient for more information or to ask her to visit the hospital for further management.

In general, digital health has the potential to improve access to health care and support a shift from hospital-based to home-based care. It may help improvement of satisfaction of care while at the same time reduce clinic visits and admissions. Evidence from randomized clinical trials and systematic reviews demonstrate favourable outcomes for a diversity of (chronic) conditions, such as COPD, heart failure, diabetes, hypertension and cancer.[16] Improvements are seen in quality of life, all-cause mortality, disease-related hospitalizations and patient autonomy. By changing the use of health care resources and medical staff, digital health also has the potential to create a reduction of costs.

Despite the positive results in several domains, there is a paucity of data on digital technology in pregnancy and childbirth care. To play a key role in the transformation of health care for both patients and caregivers in pregnancy care, unaddressed questions must be answered. Can it enhance antenatal care to deliver the quality that is required to result in equal or even better health outcomes?

In this thesis we explore the questions and expectations that arise when digital technology meets healthcare for pregnant women.

DIGITAL HEALTH IN PREGNANCY CARE

At the start of our studies in 2016, we gathered all available evidence regarding use of eHealth in obstetric care in a literature search. We learned that eHealth was used in different domains of perinatal care; for information purpose, lifestyle improvement, diabetes care, mental health, telemonitoring and improvement of care in low- and middle-income countries (Figure 1).

Fifteen studies described the characteristics of users of eHealth in their reproductive years. Around 88% of pregnant women owned a smartphone and 50-98% uses websites and apps for information on pregnancy. Women's attitude towards medical information on the Internet is favourable, irrespective of age, education or social support. They value web-based medical information as moderately reliable and as helpful in the conversation with their caregiver on pregnancy subjects. Using this exploration of eHealth users, we concluded that eHealth may be helpful to address questions and assist in decision support for complicated pregnancies.

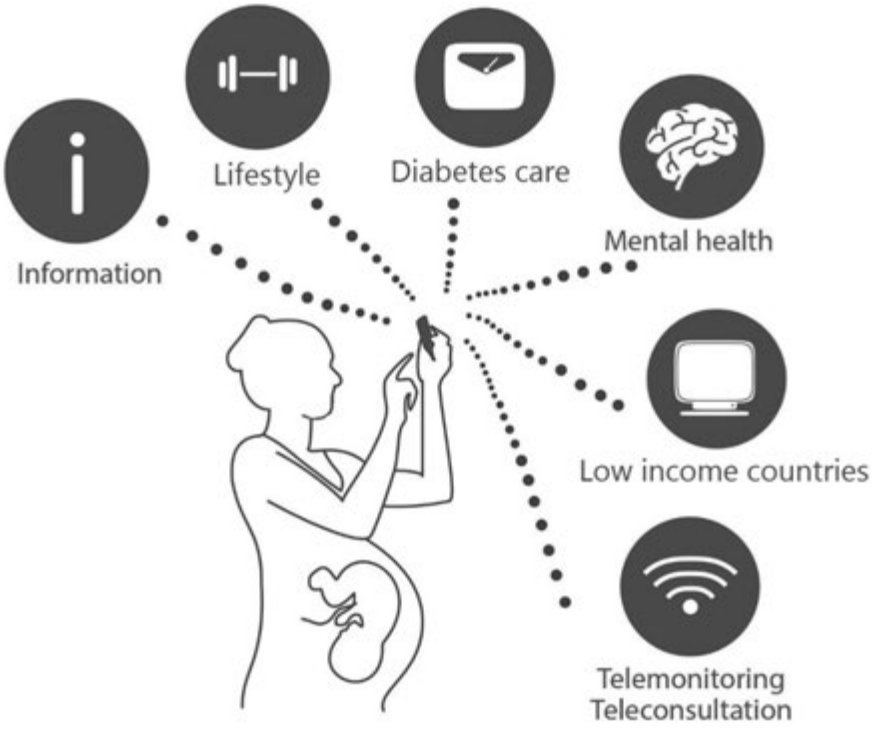

Figure 1: Six domains of pregnancy and childbirth care with use of eHealth

In **chapter 2**, we describe the results of the literature research as the present knowledge on eHealth use in perinatal care including users' characteristics and the remaining 5 domains (Figure 1).

PART 1: TELEMONITORING OF PREGNANT WOMEN AT RISK OF PREECLAMPSIA

In **Part 1** of this thesis, we describe the role of home telemonitoring of blood pressure for women at risk of preeclampsia. Telemonitoring could be an important solution to deal with the challenges resulting from frequent antenatal visits and admissions. In order to improve care for pregnant women with underlying risk factors of hypertension, we developed a digital tool to enhance prenatal care. This telemonitoring platform allows for the exchange of repeated blood pressure measurements in combination with preeclampsia symptom reporting. Values that exceed the predefined thresholds result in alerts on the monitoring dashboard for health care providers, who can contact the participant for further management. International guidelines recommend self-monitoring of blood pressure in women with gestational hypertension.[17] Research has shown that pregnant women are able to record blood pressure accurately at home and are willing to take repeated self-measurements.

Moreover, a vast majority of women with hypertension in pregnancy reported they would like to be involved in the management of their condition.[18]

Accurate measurement of blood pressure during pregnancy is essential to assist in decision making for both maternal and fetal/neonatal health. As vascular and hemodynamic changes occur in pregnancy, guidelines recommend that devices need to be validated before use in a pregnant population and specifically for pregnant women with pre-eclampsia.[19,20] In the developmental phase of our platform, we performed a validation study of two automated blood pressure monitors with Bluetooth for the connection with a smartphone application, which is described in **Chapter 3**.

The telemonitoring platform, consisting of a smartphone application and connected BP monitor, was subsequently tested in a group of low-risk pregnant women, without risk factors for hypertension. The objective was to assess participant compliance, efficacy of the automatic alert system and the usability and user satisfaction of the platform. The results of this feasibility study are outlined in **Chapter 4**.

In **Chapter 5** we aim to assess the effects of our telemonitoring platform in women at high risk for hypertensive complications in pregnancy. This is the SAFE@HOME study. We compared a prospective cohort of pregnant women with telemonitoring and a predefined reduced antenatal visit schedule to a retrospective cohort of women managed with usual care, without self-monitoring of blood pressure. Outcomes of interest are healthcare consumption, user experiences and maternal and neonatal perinatal outcomes.

In **Chapter 6** we describe the economic evaluation of the results of the digital health study of Chapter 5.

Furthermore, we assessed the experiences of the participants in the SAFE@HOME study with both surveys and interviews. This mixed-models study is presented in **Chapter 7**.

PART 2: TELEMONITORING OF PREGNANT WOMEN WITH COMPLICATIONS IN PREGNANCY

The **second part** of the thesis focuses on pregnant women with complications requiring daily monitoring of vital parameters of both mother and fetus until delivery. In the Netherlands, obstetric departments started to provide domiciliary care or “home monitoring” to risk pregnancies requiring daily monitoring. from 1990 onwards. As an alternative to clinical admission, home monitoring involved hospital-employed midwives or nurses visiting pregnant women with complications at home, on a daily basis, to perform medical tests, including CTG, and discuss results with a supervising gynaecologist. Multiple randomised

trials have proved that home monitoring with home visits is feasible and safe regarding perinatal outcome.[21,22] These trials demonstrated satisfactory outcomes for both mother and child but also that daily visits are time consuming and therefore expensive.

Again, telemonitoring may be an important solution as a replacement of hospital admission in this high risk pregnancy group. In women with fetal growth restriction, preeclampsia, preterm rupture of membranes and fetal anomalies, daily monitoring is required to assess fetal and maternal condition. Cardiotocography is needed for this assessment, next to blood pressure and urinary and blood analysis. The development and availability of a wireless, portable CTG system (Sense4Baby) has facilitated self-monitoring of fetal heart rate and uterine contractions. A considerable amount of time could be saved when the patient will take the measurements of CTG and blood pressure at home. These measurements are evaluated in the clinic by professionals on daily basis. This form of telemonitoring could therefore reduce costs and might offer an acceptable substitution to hospital admission from the patient's point of view. However, up to now there are clinical trials evaluating safety, patient and professional satisfaction and cost-effectiveness of this novel strategy in high-risk pregnancy.

Patients' involvement in the development and implementation of e-Health strategies provides insights to improve the use in daily practice. In **Chapter 8**, we describe the experiences of pregnant women during either hospital admission because of pregnancy complications, opposed to women who participated in a pilot with telemonitoring.

Currently, a number of obstetrics units in the Netherlands offer home monitoring and telemonitoring to women with pregnancy complications. **Chapter 9** is the report of a nationwide survey to all Dutch obstetric departments to determine the number of centres that provide home- and telemonitoring, and to identify the current practice of out-of-hospital care in high-risk pregnancy.

In **Chapter 10**, the protocol of the HOTEL trial is described: **Ho**spital care versus **Tel**emonitoring in high-risk pregnancy. This multicentre randomized controlled trial aims to compare telemonitoring at the patient's home versus hospital admission with regard to perinatal outcome, patient satisfaction, preference of care and cost-effectiveness.

The thesis is concluded by a general discussion of all results. The implications of the results will be discussed with additional considerations regarding the use of digital health in pregnancy and childbirth care. Lastly, discussed themes in this discussion are concluded with several recommendations for clinical practice and research in the years to come (**Chapter 11**).

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CHAPTER 2

E-HEALTH AS THE NEXT GENERATION PERINATAL CARE: AN OVERVIEW OF THE LITERATURE

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ABSTRACT

Background

Unrestricted by time and place, e-health applications provide solutions for patient empowerment and value based health care. Women in the reproductive age are particularly frequent users of Internet, social media and smartphone applications. Therefore, the pregnant patient seems to be a prime candidate for e-health supported health care with telemedicine for fetal and maternal conditions.

Objective

This study aims to review the current literature on e-health developments in pregnancy in order to assess this new generation of perinatal care.

Methods

We conducted a systematic literature search of studies on e-health technology in perinatal care in PubMed and EMBASE in June 2017. Studies reporting the use of e-health during prenatal, perinatal and postnatal care were included. Given the heterogeneity in study methods, used technologies and outcome measurements, results were analysed and presented in a narrative overview of the literature.

Results

The literature search provided 71 studies of interest. These studies were categorized in six domains: Information and e-health use, Lifestyle (gestational weight gain, exercise and smoking cessation), Gestational diabetes, Mental health, Low- and middle income countries and Telemonitoring/teleconsulting. Most studies in gestational diabetes and mental health show that e-health applications are good alternatives to standard practice. Examples are interactive blood glucose management with remote care using smartphones, telephone screening for postnatal depression and web-based cognitive behavioural therapy. Applications and exercise programs show a direction towards less gestational weight gain, increase in step count and increase in smoking abstinence. Multiple studies describe novel systems to enable home fetal monitoring with cardiotocography and uterine activity. However, only few studies assess outcomes in terms of fetal monitoring safety and efficacy in high risk pregnancy. Patients and clinicians report good overall satisfaction with new strategies that enable the shift from hospital-centered to patient-centered care.

Conclusions

This review showed that e-health interventions have a very broad, multilevel field of application focused on perinatal care in all its aspects. Most of the reviewed 71 articles were published after 2013, suggesting this novel type of care is an important topic of clinical and scientific relevance. Despite the promising preliminary results as presented, we accentuate

the need for evidence for health outcomes, patient satisfaction and the impact on costs of the possibilities of e-health interventions in perinatal care. In general, the combination of increased patient empowerment and home pregnancy care could lead to more satisfaction and efficiency. Despite the challenges of privacy, liability and costs, e-health is very likely to disperse globally in the next decade and it has the potential to deliver a revolution in perinatal care.

INTRODUCTION: E-HEALTH: A NEW OPPORTUNITY?

Health care is facing the emergence of a new range of systems, services and applications using electronic communication. E-health is the network of technology applications regarding health issues, including e.g. web-based informative programs, remote monitoring, teleconsultation and mobile device supported care.[1] As the health care costs in developed countries continue to increase, policies for cost reduction without concessions to the quality of care are being imposed. Unrestricted by time and place, e-health applications also provide solutions for patient empowerment and value based health care.[2] Patient empowerment is assumed to improve patient participation in medical decision-making, commitment to treatment and thus health outcomes.[3-5] The boost in patient engagement can be an important factor for the improvement of quality of care and patient safety.[6]

Young women in their reproductive years are frequent users of Internet, social media and smartphone apps.[7] The Internet is ever more utilized for the search of health information on prenatal, perinatal and postnatal topics.[8] Furthermore, the web is also used as a forum for the exchange of experiences and peer support.[9] Figure 1 shows multiple domains of perinatal care in which e-health is already being used by patients and health care providers.

Protocols of professionals' associations and institutions contain little communication regarding e-health. No statements are made regarding e-health in guidelines from the British Royal College of Obstetricians and Gynaecologists (RCOG), the National Institute for Health and Care Excellence (NICE) and the American College of Obstetrics and Gynecology (ACOG). The Dutch Association of Obstetrics and Gynecology notes that "developments in e-health should be actively implemented in obstetric healthcare" to "induce the shift of scheduled care to the home setting" and thus lower the in-hospital care burden.[10]

E-health has the potential to fulfil a key role in the transformation of the healthcare system for both patients and care givers. However, questions are raised if e-health can deliver the quality of care that is required to remain or even improve health outcomes. It is evident that there is a need for guidance and management of quality standards. Issues of costs and reimbursement, safety of data collection and storage, privacy and reliability of information on websites and in apps should also be taken into account.
Our aim is to provide a comprehensive and contemporary overview of the literature on e-health in perinatal care and assess the applicability, advantages, limitations and future of this new generation of pregnancy care.

METHODS

A systematic literature search was performed in PubMed and EMBASE in June 2017, combining various synonyms for perinatal care and telemedicine and e-health (See Multimedia Appendix 1 for the search strategy). Studies reporting the use of e-health during prenatal, perinatal and postnatal care were included. Because of the rapid developments in this field and our contemporary scope, we excluded articles describing outdated technologies, for example fax communication, phonocardiography and home visits or home care. Screening and reviewing the abstracts and full articles was done by two independent authors (JH and KG). Given the heterogeneity in study methods, used technologies and outcome measurements, results were analysed and presented in a narrative overview of the literature.

RESULTS

Literature search and reference screening provided 71 studies of interest (See Multimedia Appendix 1 for flow diagram of selection of studies). All articles were categorized in six domains, which will be addressed accordingly: Information and e-health use, Lifestyle (gestational weight gain, exercise and smoking cessation), Gestational Diabetes, Mental Health, Low- and middle income countries and Telemonitoring/teleconsulting (See also Figure 1). Table 1 and 2 show the overview of 71 publications in six domains of perinatal care in which e-health use in patient care was described, implemented or compared with standard care.

Information and e-health use in pregnancy

In 15 studies the characteristics of e-health users in the perinatal period were described (Table 1). Around 88% (31 of 35 participants) owned a smartphone.[11] Usage of websites and pregnancy apps for medical information varies from 50-98%.7,[11-14] Online information seeking behavior is common in pregnant women in general and it is not restricted to women with a special profile based on age, education or social support.[7] Increased knowledge on pregnancy complications has also shown to reduce maternal anxiety and costly hospital visits. [15 16] Factors associated with app use in pregnancy are younger age, nulliparity, lower self-rated health and higher education. Furthermore, 25% (56/219) of questioned women showed interest in a tailored pregnancy app initiated by their healthcare provider.[7,14]

The most searched topics are fetal development, pregnancy complications, healthy lifestyle during pregnancy, generic and specific guidance/advices during pregnancy and lactation.[13,17] Although they value the online medical information as moderately reliable, 71 to 75% (582/800) of the women do not discuss the information found on Internet with their gynecologist.[17,18] One study reported that their lifestyle app helped women to initiate the

conversation with their health care giver on this subject.[19]

There is an increasing use of Internet for health information, including the perinatal period. However, websites are often contradictory and this may lead to confusion.[20] E-health may be helpful to address questions through informative websites, apps and peer support platforms designed by health professionals. Furthermore, e-health may provide possibilities for decision support in more complicated pregnancies.[21]

Table 1: Information and e-health use in pregnancy: overview of the literature

First author, year	Methods	n =	Technology / e-health intervention
Sayakhot, 2016 [12]	Systematic review (with 7 cross sectional studies)	3,359	Patients' use of internet for pregnancy information
Ledford 2016 [22]	RCT pilot	150	App for pregnancy education and record keeping
Walker 2013 [15]	Prospective cohort	8	Website for education on placental complications
Bush 2017 [23]	Before-after study	85	Prenatal care app use and user engagement
Wallwiener 2016 [7]	Cross sectional	220	Surveys and questionnaires on use of e-health (smartphones, Internet, apps) during pregnancy
Scaioli 2015 [13]		1,347	
Peragallo 2015 [24]		100	
Lee 2016[14]		193	
Lupton 2016 [25]		410	
Narasimhulu 2016 [17]		586	
Goetz 2017 [26]	Qualitative research	total = 128	Focus groups and interviews on e-health use and implementation (in pregnant women, men and clinicians)
Willcox 2015 [27]			
Rodger 2013 [11]			
Mackert 2015 [28]			
Lupton 2016 [25]			

Health outcome after e-health intervention

The effect on health is the most important issue to address in the effective implementation of e-health in perinatal care. Parameters for quality standards include disease outcomes, enhancing patient adherence to treatment, reducing overuse and increasing access to care.[29] Results of the search showed that most publications focus on the improvement of lifestyle (gestational weight gain, exercise, smoking cessation), gestational diabetes monitoring, mental health, care in lower and middle income countries and telemonitoring.

Lifestyle

Our search provided 13 publications describing health outcomes for e-health interventions on lifestyle during pregnancy (Table 2). Pursuing a healthy lifestyle has proven to be beneficial for pregnancy outcomes such as preterm birth, gestational diabetes or pre-eclampsia.[30-32] Participant motivation, reducing the dropout rate and sustainability of long-term results

are notoriously difficult in lifestyle studies. Smartphone technologies provide features to overcome these obstacles. Results from feasibility studies show good acceptability, adherence and engagement for e-health interventions for healthy gestational weight gain and physical activity, favoring an app over a website.[33,34] Physical activity trials with tailored SMS services resulted in an increase in step count up to four times more than in the control group. Also, e-health interventions resulted in better-perceived health in pregnancy and lower, healthier gestational weight gain in both non-obese (7.8 kg versus 9.7 kg) and obese women (6.65 kg versus 9.74 kg).[35-37] Dietary apps directed at healthy gestational weight gain are still in developmental and experimental phase.[27,38,39]

Smoking during pregnancy increases the risk of unfavorable pregnancy outcomes. In 2010, approximately 10% of the women smoked cigarettes during pregnancy, especially younger, non-Caucasian mothers of a lower social economic status[40,41] The 2016 review by Heminger et al. summarizes the studies performed on short message service programs and mobile applications for smoking cessation in pregnancy.[42] Women participating in SMS cessation programs report relatively high abstinence of 38% in the first week, and 54% in the second week (n=20). Biochemically confirmed abstinence rates were 12.5% in participants compared to 7.8% in controls (n=207). Mobile applications were preferred over SMS-driven programs, as seen in over 10.000 installations of apps compared to 20-800 registrations in SMS programs.

Gestational Diabetes

About 5-7% of all pregnancies are complicated by Gestational Diabetes Mellitus (GDM) in the United Kingdom and United States (range 1-25%).[43] Pregnancies with GDM are associated with perinatal complications such as caesarean section, shoulder dystocia and neonatal hypoglycemia. Extensive glucose monitoring during pregnancy is a burden for both patients and health care budgets. E-health in GDM care has evolved most notably of all perinatal applications of e-health the last three years.[44] We found 13 studies on this topic, including two systematic reviews (Table 2). Developments involve smartphone facilitated remote blood glucose monitoring, management of medication schedules through web-based or SMS-facilitated feedback systems and telephone review service to support and supervise glycemic control. [45-51] Overall, studies showed a decrease in planned and unplanned visits by 50-66%, while no unfavorable differences in glycemic control, maternal and neonatal outcomes occurred.[47-49,52] Two recent systematic reviews with meta-analysis confirms these results.[53,54] No cost–effectiveness analysis was performed due to insufficient data. There is also increasing evidence of GDM as a risk factor for type two diabetes later in life[55] E-health programs for follow up of women with a history of GDM are being developed, but need to be examined more thoroughly.[45]

Table 2. Health outcome of electronic health (eHealth) use in lifestyle and gestational diabetes mellitus management in pregnancy: overview of the literature.

First author, year	Methods	N =	Technology / e-health intervention
Lifestyle: Gestational weight gain, exercise, smoking cessation (13 studies)			
O'Brien 2014 [79]	Systematic review (with 7 studies)	33	Technology supported diet and lifestyle interventions
Pollak 2014 [80]	RCT	33	SMS programs on healthy lifestyle
Soltani 2015 [35]	RCT	14	SMS for heathy lifestyle for BMI >30
Graham 2017 [81]	RCT	1,335	Internet-based platform to prevent excessive weight gain
Hayman 2017 [34]	RCT	77	Web based physical activity intervention
Huberty 2016 [82]	RCT	80	SMS programs to increase physical activity
Willcox 2017 [37]	RCT	91	Healthy gestational weight gain for obese pregnancies
Knight 2015 [19]	One group pilot	10	App with information for lifestyle behavior
Waring 2014 [33]	Cross sectional	64	Survey on lifestyle app or website
Choi 2015 [36]	RCT pilot	30	Activity app + pedometer wearable
Lewis 2011 [83]	Cohort	37	Exercise with SMS or App based support
Guo 2016 [84]	One group pilot	50	Video program with yoga via Facebook or DVD
Heminger 2016 [42]	Systematic review (with 7 RCTs)	702	SMS or App support on smoking: quitting date, relapse, information, daily messages
Gestational diabetes (13 studies)			
Ming 2016 [54]	Systematic review (with 7 RCTs)	579	Telemedicine for glucose monitoring
Rasekaba 2015 [53]	Systematic review (with 3 RCTs)	243	Telemedicine for glucose monitoring
Kruger 2003 [85]	RCT	18	Telemedicine for glucose monitoring
Dalfra 2009 [86]	RCT	276	Telemedicine for glucose monitoring
Perez-Ferre 2010 [52]	RCT	100	Telemedicine for glucose monitoring
Wojcicki 2004 [87]	RCT	30	Telemedicine for glucose monitoring
Carral 2015 [49]	Prospective cohort	104	Web-based telemedicine system
Given 2015 [50]	Feasibility study	50	Web-based telemedicine system
Nicholson 2016 [88]	Feasibility study	23	Web –based self monitoring, diary
Mackillop 2014 [51]	Pilot study	48	Smartphone app with blood glucose meter
Ganapathy 2016 [89]	Pilot study	50	Remote blood pressure measurements
Khorshidi 2015 [45]	RCT	80	Post partum screening after GDM
Harrison 2017[90]	Survey + interviews	70	Acceptability of telemedicine in GDM

Legend: RCT: randomized controlled trial; SMS: short message services. BMI: body mass index; GDM: gestational diabetes mellitus.

Mental Health

E-mental health has already proven to be successful in general population mental health management.[56] In 16 studies the applicability on screening for and treatment of postpartum depression was investigated (Table 2). The prevalence of postpartum depression is 3-15%. These women are reluctant to seek medical attention despite the heavy burden of disease, most notably because of the fear of their child being taken away from them.[57,58] Both screening with telephone (alpha coefficients of 0.72-0.94), app (sensitivity 72% and specificity 73%) and iPads were found feasible and acceptable [58-60]. E-health programs (e.g. online sessions based on cognitive behavior therapy) effectuate significant reductions in the depression scales and on symptom scores compared to treatment as usual.[61-64] Besides this significant effect size favoring e-health, in one intervention group the depression scores reduced also more quickly compared to the waiting list comparator group[63]. Perceptions of peer and social support significantly improved and higher support was significantly related with lower depression symptoms.[65] An antenatal, first trimester e-health intervention on depressive symptoms showed 80% intervention response and 60% remission (n=12).[63]

Low and middle-income countries

Limited resources and poor information is still leading to preventable maternal and neonatal deaths in low and middle-income countries. The availability of mobile phones (in Africa and South-East-Asia over 69-90%) gives rise to the implementation of e-health interventions and remote care. For more detailed information in this distinct population where e-health applications are widely used, we refer to two recently published systematic reviews (Table 2). In summary: the interventions did increase antenatal care attendance, facility and service utilization, skilled support at birth and vaccination rate.[66] Most of included studies were of poor methodological quality or did not assess health outcomes.[67] Insufficient information was provided to evaluate the impact of e-health solutions on maternal and fetal outcomes in these countries.[67]

Telemonitoring and teleconsulting

Telemonitoring of pregnancy is perceived to be one of the most promising answers to the possibilities of e-health in pregnancy. Several hardware and software systems involving more complex remote monitoring are described lately (Table 2). An integrated system for maternal monitoring of glucose, weight, pulse and blood pressure and a chat feature for clinician-patient contact is now in test.[68] Yi et al. developed an Android based mobile terminal for wireless fetal monitoring and uterine contractions tracking.[69] Using this system, patients in rural areas are provided with telemonitoring without travelling or hospitalization. Several other telemonitoring devices for cardiotocography have been tested in pilot settings or prospective cohorts and found feasible.[70-72] Currently the effects of maternal and fetal telemonitoring in high-risk pregnancies on outcome, satisfaction and costs are under research compared to hospital admission (the HOTEL trial, registered under No. NTR6076).

Table 3. Health outcome of electronic health (eHealth) use in electronic mental (e-mental) health, low- and middle-income countries, and telemonitoring and teleconsultation in pregnancy

E-mental health (16 studies)			
Lau 2016 [64]	Systematic review (with 8 RCTs)	1,523	Therapist-Supported Internet-Based Cognitive Behavior Therapy Among Postpartum Women
Lee 2016 [61]	Systematic review (with 4 RCTs)	1,274	Cognitive behavioral therapy with internet
Ashford 2016 [63]	Systematic review (with 11 studies)	1.537	Web based perinatal mental health interventions
Milgrom 2016 [91]	RCT	43	Cognitive behavioral therapy with internet
Ngai 2015 [92]	RCT	397	Telephone-Based Cognitive-Behavioral Therapy
Shamshiri 2015 [93]	RCT	54	Telephone-Based Cognitive-Behavioral Therapy
Kingston 2017[60]	RCT	636	Acceptability of e-screening for mental health
Fontein 2016 [94]	Before-after study	433	Website for maternal stress prevention
Jimenez 2015 [59]	Cohort	1,880	App screening for post partum depression
Posmontier 2016[62]	Cohort	61	Telephone-Administered Psychotherapy
Letourneau 2015[65]	Cohort	64	Telephone-based peer support intervention
Broom 2015 [95]	Observational	54	Text messaging in post partum depression
Mitchell 2006[58]	Cross sectional	106	Telephone screening for postpartum depression
Figueiredo 2015 [96]	Cross sectional	90	Telephone screening for postpartum depression
Pugh 2014 [97]	Case study	1	Therapeutic assistance with e-mail and SMS
Pineros 2015 [98]	Qualitative	25	mHealth creening for post partum depression
Low and middle income countries (2 studies)			
Lee 2015 [67]	2 systematic reviews with 36 studies	34,149	mHealth interventions for prenatal, birth and postnatal period in low and middle income countries
Sondaal 2016 [66]			
Telemonitoring / teleconsulting (12 studies)			
Tapia 2015 [75]	RCT	153	Wireless antepartum maternal-fetal monitoring
Pflugeisen 2016 [74]	Non-RCT	1.058	Prenatal care with virtual visits and mHealth
Ivey 2015 [99]	Cohort	155	Teleconsultation with tertiary center
Cuneo 2017[100]	Cohort	125	Home monitoring for anti-SSA+ fetal hearts
Rauf 2011[73]	Cohort	70	Fetal monitoring system for induction of labor
Krishnamurti 2017[101]	Cohort	16	Smartphone app with information and symptom scores
Rhoads 2017[102]	Non RCT	50	Telemonitoring of post partum hypertension
Kerner 2004[77]	Feasibility study	36	Self-administered fetal heart rate monitoring
Marko 2016 [103]	Feasibility study	8	Remote monitored pregnancy care (BP, weight)
Marko 2016 [76]	Controlled trial	100	Prenatal care with app and telemonitoring
Lanssens 2017 [104]	Cohort	166	Remote monitoring of hypertension
Pflugeisen 2017[105]	Cross sectional	171	Satisfaction with Virtual Obstetric Care

Legend: RCT: randomized controlled trial; SMS: short message services

In a pilot with remote monitoring with transabdominal f-ECG after induction with dinoprostone pessaries (n=70), successful monitoring was obtained in 89%.[73] Three women were recalled to the hospital due to suspicious f-ECG, of which in two cases caesarean section was indicated. 'Virtual Obstetric Care' with normal visits combined with teleconferencing visits for low-risk pregnancy showed no increased risks in health outcomes besides an increase in preeclampsia diagnosis.[74] Another demonstration project describes a promising system of a wirelessly enabled maternal-fetal monitoring system "MiBebe", used for the improvement of perinatal care in rural regions in Mexico. In the group of 153 high-risk pregnancies, the remote monitoring in 74 patients resulted in markedly increased adherence to antenatal visits with no adverse health outcomes compared to usual care.[75] One pilot describes an alternative prenatal care schedule, including an integrated technology platform (mobile app, wireless weight scale and BP cuff), leading to a 43% reduction in outpatient visits (8 vs 14 visits).[76] There was an increase in satisfaction, patient engagement and no change in perinatal outcome despite the decrease in face-to-face contact.[76] Remote monitoring and consultation can potentially reduce outpatient visits for antenatal consultation as well as hospitalization for certain clinical reasons. We see this in managing gestational diabetes with glucose monitoring but also in fetal monitoring for IUGR.[53,77] A model of cost-effectiveness analysis in a tertiary hospital (Ghent, Belgium) predicted a cost-reduction of 145,822 euro per year achieved by introducing home monitoring in high risk pregnancy.[78]

Patient and caregiver experience

Examining patients' satisfaction with e-health interventions, users describe high convenience and acceptance resulting in more patient activation and education. Patients report less concerns, anxiety and are comfortable with fewer clinic visits. Satisfaction rates vary between 86-95% in e-mental health studies and 90% (46/51) in home-monitored induction patients, who were very glad to stay in their own, homely ambience as long as possible.[73,79]
On the health care providers' point of view, adaptation of obstetricians and midwives to e-health solutions has not been widely described. Only one qualitative study interviewed 12 health care providers in obstetric departments. Concerns were raised on implementation barriers and potential medico-legal risks but if addressed properly, implementation was considered feasible. Some clinicians admitted to have insufficient familiarity and skill with e-health limiting their engagement and comprehension of the possibilities that e-health technologies can confer to perinatal care. Overall these clinicians regarded telemedicine as an additional parallel service rather than integrated into the antenatal care model.[27]

DISCUSSION

Principal findings

By providing this overview of the literature, we aimed to assess the applicability, advantages and limitations of the use of e-health in perinatal care. This review showed that e-health interventions have a very broad, multilevel field of application focused on perinatal care in all its aspects. Most of the reviewed 71 articles were published after 2013, suggesting this novel type of care is an important topic of clinical and scientific relevance. Women of reproductive age seem to be interested in e-health as shown by their frequent use of smartphone, internet and apps and searches for pregnancy information. Most health outcomes for perinatal e-health interventions were generally positive, either resulting in positive effects (lifestyle, mental health) or providing multiple advantages while health outcomes were found equal (diabetes care). The implementation of telemonitoring was not studied extensively but research provided important effects and advantages on facilitation of new care models. Patient and care provider satisfaction with e-health interventions rates are generally good with rates up to 95%.

Additional considerations

Despite the promising preliminary results as reviewed above, research in e-health has progressed much slower than developments in the health technology industry. A great amount of the reviewed articles on this subject addressed more than health outcomes or satisfaction rates alone. Advances in (implementation of) apps and devices and patient-generated data are retained by legal and financial concerns.

Possible privacy risks involve a lack of control to collection of data and the use by third parties afterwards. In the United States, e-health legislation, secured in the Fair Information Practice principles (part of the Health Insurance Portability and Accountability Act), is lacking protection for endpoint users: the patients. End-to-end data encryption can be used to protect the useful patient data. Combined with authentication and access control mechanisms for patients as well as care providers, e-health technologies can further enhance final security control.[106] The development of TELE-MED Act (2015), may accelerate the removal of barriers and limitations regarding use of telehealth between different states in the US.[107]

In the framework of European law, e-health is simultaneously a healthcare service and an information service with corresponding legislation[108.] E-health developers have to mind general legislation regarding privacy protection (Dir 95/46/EC, Arts. 8-12), electronic identification services, e-Commerce directive (e.g. online contracting), safety requirements of medical devices and general product safety and liability requirements. In answer to the inter-state developments in e-health care, the Cross Border Directive was initiated in 2011 in the European Union. The objective of the initiatives within this directive is to turn telemedicine into a standard medical service, accessible to every European patient and fully

covered by the respective social security system. Difficulties arise on liability and creating uniformed rules in the European Union, as Member States have very intrinsic differences in national rules on health care, privacy and liability. One advice would be for each Member State to provide a legal framework for telemedicine, while the role of the EU would be limited to regulation[108].

The costs associated with development, purchase and maintenance of e-health equipment have dropped in recent years due to technological advancements.[107] Primary investments to implement e-health in perinatal care are now attributed to personnel costs for both providers and technical support. However, to deliver care with the help of e-health can also create savings on personnel costs and clinic visits. A systematic review of economic evaluation in telehealth solutions concluded that 29 out of 39 studies (74%) reported cost-effective, economically beneficial e-health interventions in different conditions and diseases. The conclusion highlighted the fact that many studies did not report all recommended economic outcome items leading to inconsistent analyses.[109]

The challenges for reimbursement are delaying the widespread adoption of e-health in all ranges of sections of hospital care. Coverage is fragmented, varying at level of country, within hospitals in the same country and within different specialties of health care.[29] Health insurance companies seem to be inclined to cover only well researched e-health interventions with according economic evaluations. The use of low-risk, inexpensive care models can operate as opportunities to objectify possible reduction in health care costs. Successes will motivate policy makers and drive the insurance market for additional coverage. Rigorous medical evidence can act as an extra stimulant, however the duration and costs of designs and trials need to be taken into consideration.[107]

Table 3. Advantages and disadvantages of e-health implementation in perinatal care

Advantages	Disadvantages	Indistinct
Patient satisfaction	Reimbursement issues	Impact on health outcome
Patient engagement	Legal issues	Impact on costs
Fewer clinic visits	Technical issues	Limited A-level evidence
Clinician satisfaction		
Remote monitoring		
Access to care in low- and middle-income countries		

Conclusion and future perspectives

This review provided an overview of e-health as the next generation perinatal care. Table 3 provides a condensed summary of the advantages (as described in Principle findings) and disadvantages (as described in Additional considerations) of the implementation of e-health in perinatal care. If e-health is to achieve its full potential, it should attain all domains of quality in care including safety, timeliness, effectiveness, efficiency and patient centeredness.

Cost-effectiveness assessment is needed to rationalize embracement and reimbursement. Policy makers should consider the international frameworks of legislation to support and implement this new form of care.

We accentuate that more research is needed, including economic evaluation of e-health interventions. Growing engagement of calls for funding have responded: more large funding associations focus on the application of e-health, warranting the qualitative impact of the studies in the application designs.[110] Also, the potential of technology raised a nearly quadrupled amount of money in venture capital funding, from $1.1 billion in 2011 to $4.3 billion in 2015.[111]

Despite the challenges of privacy, liability and costs, e-health is very likely to disperse globally in the next decade. Some even state healthcare is approaching a tipping point.[112] The current shift to patient-centered care and increased patient empowerment underlines the need for revising current medical practice. E-health has the potential to be integrated into standard care and deliver a revolution in perinatal health.

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PART I

TELEMONITORING OF PREGNANT WOMEN AT RISK OF PREECLAMPSIA

CHAPTER 3

VALIDATION OF THE IHEALTH TRACK AND OMRON HEM-9210T AUTOMATED BLOOD PRESSURE DEVICES FOR USE IN PREGNANCY

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ABSTRACT

Objective

Self monitoring of blood pressure in pregnancy is increasingly popular with both health care professionals and patients. We assessed the validity of the iHealth Track and Omron HEM-9210T automated blood pressure devices (with Bluetooth connectivity) for the use in telemonitoring of blood pressure in pregnancy.

Methods

In this prospective observational study, the revised 2010 International Protocol of the European Hypertension Society (EHS) was used for the validation of the two devices against auscultatory sphygmomanometry by two independent observers who took 13 same arm measurements in 33 pregnant women, of which 10 were diagnosed with preeclampsia. The measurements were alternated between the test device and a calibrated aneroid sphygmomanometer following the protocol. Both automated devices were assessed sequentially in the same women.

Results

In the group of 33 women, the iHealth Track passed the EHS 2010 validation criteria with 86/98/99 of 99 device-observer systolic measurement comparisons and 88/96/98 of 99 device-observer diastolic measurement comparisons within the 5/10/15 mmHg boundaries respectively. The Omron HEM-9210T passed the same criteria with 85/94/99 of 99 device-observer systolic measurement comparisons and 82/95/99 of 99 device-observer diastolic measurement comparisons.

Conclusions

The iHealth Track and Omron HEM-9210T automated blood pressure monitors are validated for use in pregnancy. These two devices can now be added to the short list of validated devices in pregnancy and can be used for self-measurement of blood pressure in a telemonitoring setting of pregnant patients with (a high risk of) hypertensive disease.

INTRODUCTION

The proportion of women at increased risk for hypertension in pregnancy is growing, caused by factors such as life style, obesity, advanced maternal age at conception and concurrent heart or kidney disease.[1]

Accurate blood pressure (BP) measurement is essential for diagnosis and management of hypertension in pregnancy. In clinical practice, BP is measured using auscultatory sphygmomanometry or using automated devices validated for use in pregnancy. Besides clinical measurements, self monitoring of BP in pregnancy is increasingly popular with both health care professionals and patients. Guidelines now recommend home monitoring for patients with chronic hypertension and gestational hypertension.[2,3] Possible advantages of home monitoring include the potential to rule out white coat hypertension, reduce the burden and costs of clinic visits and enhance patient satisfaction and autonomy.[1] With help of telemonitoring, women at high risk for or even established hypertensive disorders of pregnancy (HDP) or preeclampsia can be monitored (more) frequently without interfering all too much with daily activities.[4] Patients' acceptability and willingness for home blood pressure measurements is generally good, as they report increased reassurance, empowerment and less anxiety.[5] Professional guidelines regarding preeclampsia caution against automated blood pressure measuring devices for establishing the diagnosis of preeclampsia and institution of treatment, because both overestimation as well as underestimation of blood pressure (BP) can occur in comparison with auscultatory measurements.[3, 6]

While numerous automated BP devices are freely available, few monitors are validated for accurate use in pregnancy with or without hypertensive disorders such as preeclampsia. It is essential that new devices are compared to gold standard measurement methods to rule out over- or underestimation of BP values during pregnancy. Previous studies found several home monitors valid for use in pregnant women, according to different international validation protocols.[7-9] Other devices did not pass validation requirements recently and are therefore not recommended for use in pregnancy. [10]

In order to offer pregnant patients an automated BP device with an integrated platform for telemonitoring of blood pressure, we chose to assess the validity of two devices according to the revised 2010 International Protocol of the European Hypertension Society. [11]

METHODS

In this prospective observational study the revised 2010 International Protocol of the European Hypertension Society was used for the validation of two different devices. This study was exempted from approval of the Medical Research Ethics Committee of the University Medical Center in Utrecht (reference number 16-637), as the Committee confirmed that the Dutch Medical Research Involving Human Subjects Act (WMO) did not apply to this study.

Device details

The iHealth Track is a fully automated oscillometric BP monitor by Andon Health Co, China. The accessory cuff can be used, according to the manual, for arm circumferences of 22-42 cm. Its Bluetooth functionality allows data synchronization with different health apps on smartphone and tablet. This monitor is previously validated in a general population according to the American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization (ANSI/AAMI/ISO) 81060-2:2013 standard.

The Omron HEM-9210T (Omron Healthcare Co. Ltd., Kyoto, Japan) is an automated oscillometric device for BP measurement on the upper arm. The wide-range cuff is used for arms 22–42 cm in circumference. Data can also be transferred to a database using Bluetooth connection. This device is validated in a general population using 85 subjects according to the ANSI/AAMI/ISO criteria.[12]

Recruitment

The EHS protocol requires 33 subjects within one specific group. Pregnant women with age over 21 years old were recruited on the maternal ward of an academic teaching hospital (Utrecht University Medical Center). All subjects were at least 25 weeks pregnant and were hospitalized for different reasons (e.g. preeclampsia, preterm rupture of membranes, need for i.v. medication) but without discomfort or contractions, as this could possibly alter blood pressure. Exclusion criteria for the validation were unclear Korotkoff sounds, arrhythmia, or arm circumference above or below the device prescription (22-42cm). A subgroup of the recruited patients was diagnosed with preeclampsia. Preeclampsia was defined as de-novo hypertension in pregnancy (a blood pressure equal to >140 and/or >90 mmHg on two separate measurements) with proteinuria or new-onset thrombocytopenia, renal insufficiency, neurological complications, liver involvement or fetal growth restriction.[13]

Procedures

Overseen by an independent supervisor [JH], measurements were performed and recorded by two observers blinded from both each other's readings and from the device readings,

after being acquainted with all devices and procedures. Subjects rested for 5 minutes in seating position before two separate observers started using two calibrated aneroid sphygmanometers (HEINE GAMMA XXL LF) as this is our Unit's gold standard since mercury sphygmanometers are prohibited for clinical use.[14] The supervisor measured the BP with the automated devices and checked the agreement of the BP values retrieved by the blinded observers. Both iHealth Track and Omron HEM-9210T were assessed sequentially in the same subjects, following this order and with 30-60s rest between readings: Entry measurements: Observer 1, Observer 2, Device, Validation measurements: Observer 1 – Observer 2 – Device - Observer 1 – Observer 2 – Device - Observer 1 – Observer 2 – Device - Observer 1 – Observer 2. The last seven measurements were analysed following the protocol.

Analysis

Observer – device differences were classified for systolic and diastolic values in three groups; within 5, 10 and 15 mmHg variability. Details of this procedure are published in the protocol[(11)]. The pass requirements of Part 1 (See Results- Table 2 and 3) state that within these 3 variability groups, of 99 device-observer measurement comparisons, at least two of 73/87/96 boundaries OR all of the 65/81/93 boundaries should be met. The pass requirements of Part 2 (See Results – Table 2 and 3) state that at least 24 of 33 subjects should have two or three absolute differences between observer and device measurements within 5 mmHg. No more than 3 subjects are allowed to have none of the absolute differences between observer and device measurements within 5 mmHg. Differences between observers and devices and 95% limits of agreement were visualized in Bland-Altman plots.

RESULTS

Thirty-three women were included in the study, of which 10 were diagnosed with preeclampsia. The characteristics are presented in Table 1.

The differences between the two observers were 0.1±2.4 mmHg for systolic and -0.1±2.5 mmHg for diastolic measures, with a range from -4 to +4 mmHg.

Table 1. Characteristics of all 33 subjects and the subgroup of 10 patients with preeclampsia

	All	**Preeclampsia**
Total women , n (%)	33	10 (30.3%)
Age (years)		
Range (Low : High)	22:40	22:39
Mean (SD)	31.0 (4.9)	30.7 (6.5)
Recruitment SBP (mmHg)		
Range (Low:High)	100:155	135:155
Mean (SD)	127.5 (16.3)	145.5 (6.7)
Recruitment DBP (mmHg)		
Range (Low:High)	50:105	80:105
Mean (SD)	78.7 (12.6)	90.7 (7.9)
Arm circumference (cm)		
Range (Low : High)	25:40	26:33
Mean (SD)	29.1 (2.6)	29.2 (2.1)
Gestational age at study day		
Mean (SD)	30.9 (3.6)	31.9 (2.9)
Body mass index pre-pregnancy (kg/m2)		
Mean (SD)	25,7 (5.4)	27.3 (4.0)
Main reason for admission, n (%)		
Preeclampsia	10 (30.3)	10 (100)
Preterm rupture of membranes	8 (24.2)	-
Fetal growth retardation	4 (12.1)	-
Asymptomatic cervical shortening	4 (12.1)	-
Fetal congenital abnormalities	2 (6.1)	-
Antepartum haemorrhage	2 (6.1)	-
Other	3 (9.1)	-
Antihypertensive medication		
n (%)	6 (18.1)	6 (60)

Legend: *DBP, diastolic blood pressure; SBP, systolic blood pressure*

Table 2. Pass requirements and validation results for **iHealth Track** *automated BP device according to the European Society of Hypertension International Protocol Revision 2010. Results are in absolute numbers (measurements in Part 1, subjects in Part 2).*

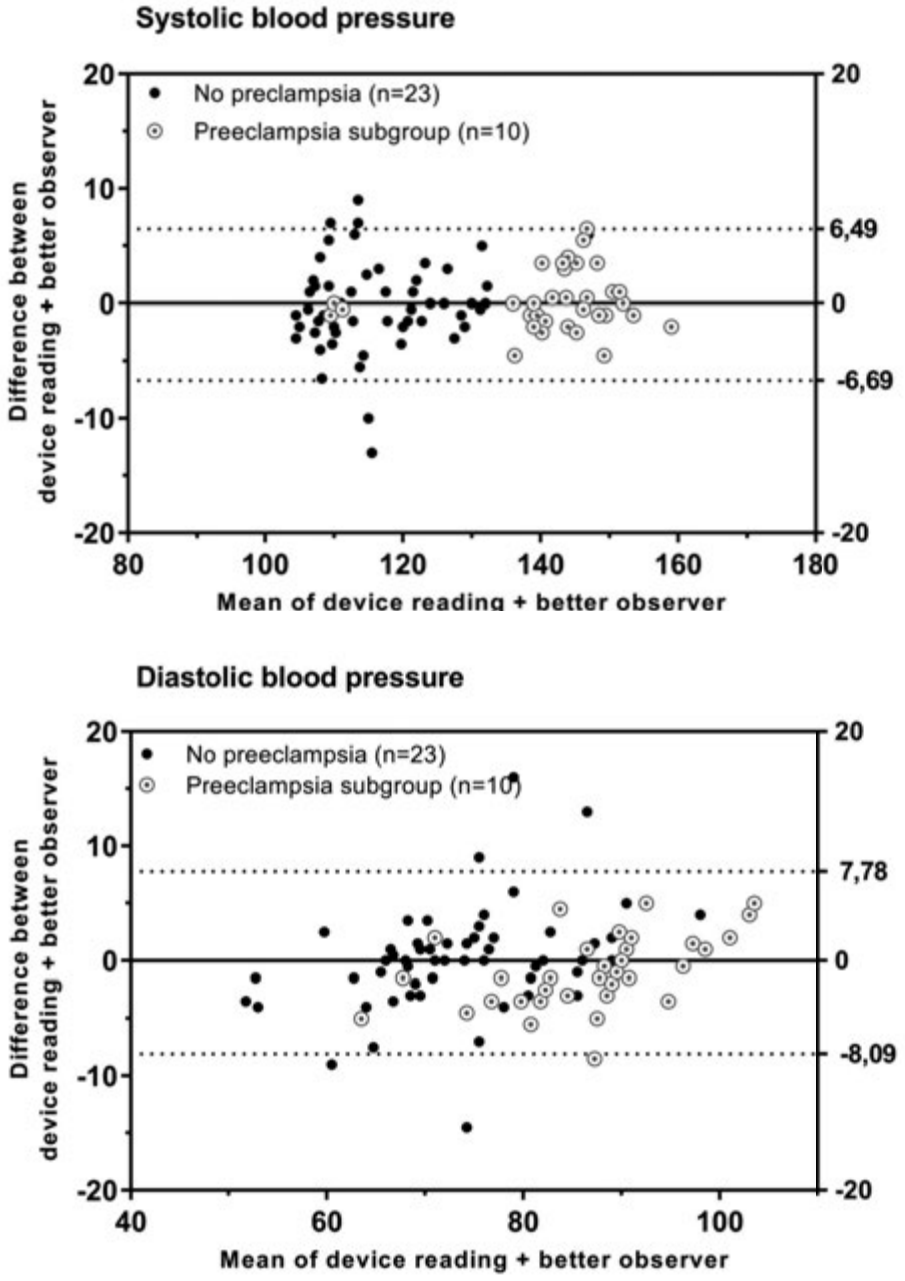
Part 1		**≤ 5 mmHg**	**≤ 10 mmHg**	**≤ 15 mmHg**	**Grade 1**	**Mean difference**	**SD**
Required	Two of	73	87	96			
	All of	65	81	93			
Achieved	SBP	86	98	99	PASS	-0,1 mmHg	3,4 mmHg
	DBP	88	96	98	PASS	-0,1 mmHg	4,0 mmHg
Part 2		**2/3 ≤ 5 mmHg**	**0/3 ≤ 5 mmHg**		**Grade 2**		**Grade 3**
Required		≥ 24	≤ 3				
Achieved	SBP	31	1		PASS		PASS
	DBP	31	1		PASS		PASS
Part 3							**PASS**

Legend: DBP, diastolic blood pressure; SBP, systolic blood pressure; SD, standard deviation

In the group of 33 women, the **iHealth Track** passed the EHS 2010 validation criteria with 86/98/99 of 99 device-observer SBP measurement comparisons and 88/96/98 of 99 device – observer DBP measurement comparisons within the 5/10/15 mmHg boundaries respectively (See Table 2 for pass requirements and results). The mean difference (SD) between the observers and the iHealth Track was -0.1 (3.4) for systolic BP and -0.1 (4.0) for diastolic PB measurements, respectively.

Bland-Altman plots of the results are shown for both systolic and diastolic blood pressure (Fig. 1) and present the differences between the iHealth Track readings and its corresponding observer readings (the better of the previous and next observer readings) plotted against the mean of the device and the better observer measurements.

Figure 1. Bland-Altman plots showing differences of systolic (upper plot) and blood pressure in pregnancy (including a subgroup with preeclampsia) between the ***iHealth Track*** *readings and the mean of two observer readings in 33 participants (n=99). The two dotted lines represent the 95% limits of agreement of the total group of 33.*



The Omron HEM-9210T passed the EHS 2010 validation criteria with 85/94/99 of 99 device-observer SBP measurement comparisons and 82/95/99 of 99 device – observer DBP measurement comparisons within the 5/10/15 mmHg boundaries respectively (See Table 3 for pass requirements and results) The mean difference (SD) between de observers and the iHealth Track was -0,8 (3,7) for systolic BP and -1,1 (-4,2) for diastolic PB measurements, respectively.

*Table 3. Pass requirements and validation results for **Omron HEM-9210T** automated BP device according to the European Society of Hypertension International Protocol Revision 2010. Results are in absolute numbers (measurements in Part 1, subjects in Part 2).*

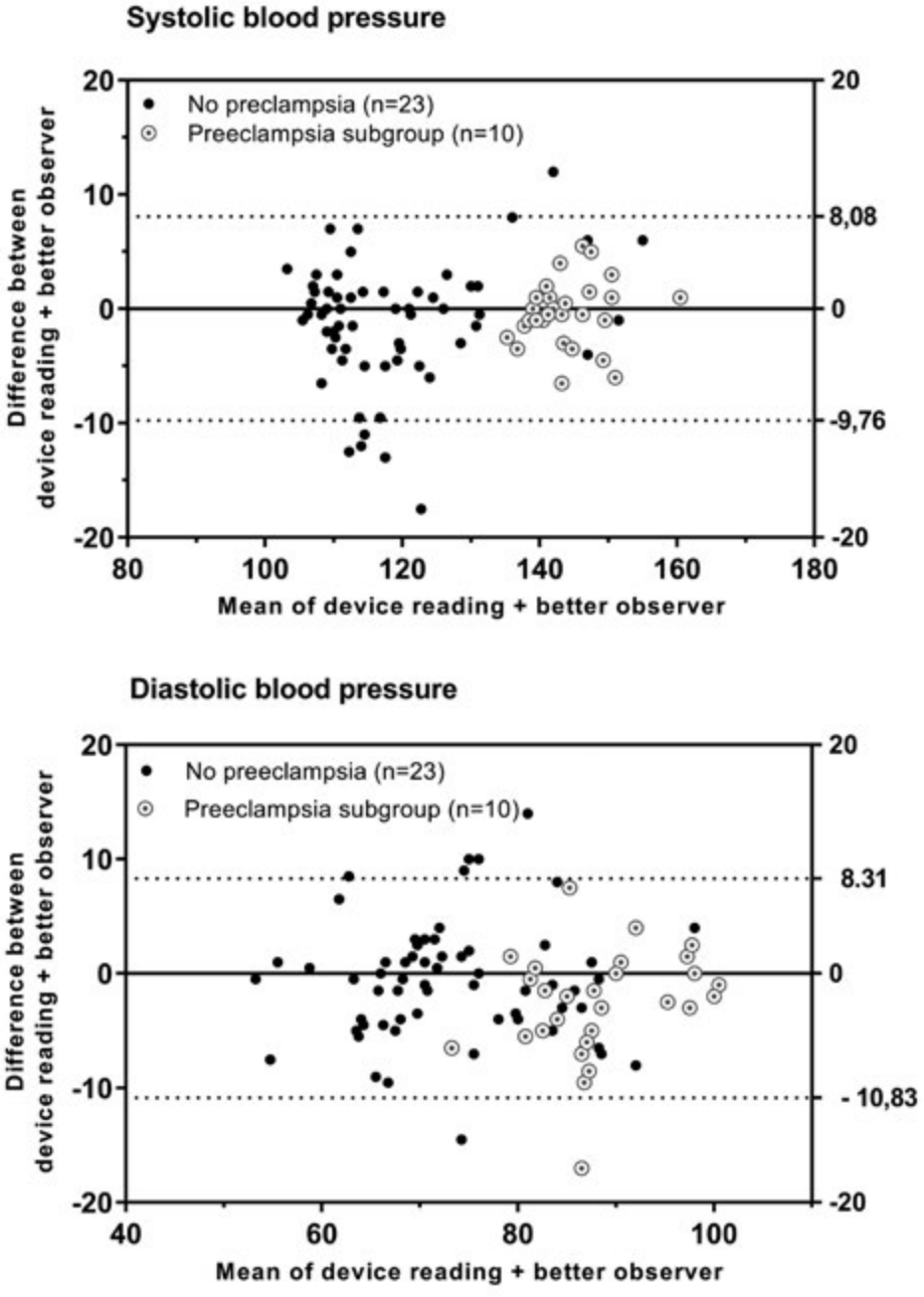
Part 1		**≤ 5 mmHg**	**≤ 10 mmHg**	**≤ 15 mmHg**	**Grade 1**	**Mean difference**	**SD**
Required	Two of	73	87	96			
	All of	65	81	93			
Achieved	SBP	85	94	99	PASS	-0,8 mmHg	3,7 mmHg
	DBP	82	95	99	PASS	-1,1 mmHg	4,2 mmHg
Part 2		**2/3 ≤ 5 mmHg**	**0/3 ≤ 5 mmHg**		**Grade 2**		**Grade 3**
Required		≥ 24	≤ 3				
Achieved	SBP	30	1		PASS		PASS
	DBP	30	0		PASS		PASS
Part 3							**PASS**

Legend: DBP, diastolic blood pressure; SBP, systolic blood pressure; SD, standard deviation

Bland-Altman plots of the results are shown for both systolic and diastolic blood pressure (Fig. 2) and present the differences between the Omron HEM-9210T readings and its corresponding observer reading (the better of the previous and next observer readings) plotted against the mean of the device and the better observer measurements.

As shown in the Bland- Altman plots for both devices (Figure 1 and Figure 2), agreement between each of the two automated devices and the better observer readings was satisfactory too in the higher BP range, as the majority of the differences is within the 95% limits of agreement. Most of these readings are from preeclampsia patients, presented by the white dotted bullets.

Figure 2. Bland-Altman plots showing differences of systolic (upper plot) and diastolic (lower plot) blood pressure in pregnancy (including a subgroup with preeclampsia) between the ***Omron HEM-9210-T*** *readings and the mean of two observer readings in 33 participants (n=99). The two dotted lines represent the 95% limits of agreement of the total group of 33.*



DISCUSSION

Key findings

This validation study shows that both the iHealth Track and the Omron HEM-9210T automated BP devices fulfill the validation requirements of the revised 2010 International Protocol of the European Hypertension Society in a population of pregnant women, including a subgroup of pregnant women with preeclampsia.

Previous studies validated the use of the iHealth Track and the Omron HEM-9210T in general populations using the ANSI/AAMI/ISO criteria.[12, 15] This validation study of a population subgroup ensures the accuracy of both devices when used in pregnancy. This allows the use of the two monitors in both clinical and home conditions of BP measuring in pregnancy.

Validation in pregnancy and preeclampsia

Altered hemodynamics of pregnant women are supposedly the reason for differences in BP readings compared to a general, non pregnant population.[16] It is therefore recommended that, prior to standard clinical use, the device has been tested specifically in pregnant patients. As mentioned before, few automated devices have been validated for use in pregnancy.[17]

Even more profound changes in hemodynamics can be found in pregnancies complicated with preeclampsia. Our study included 10 (out of a total of 33) women with preeclampsia and a wide range of blood pressure values up to 160 mmHg systolic and 110 mmHg diastolic. This resulted in a wider range of baseline blood pressure values, including severe hypertension, eventually leading to a more valuable report. However, this particular subgroup of 10 preeclampsia patients does not allow direct extrapolation to validation of these two devices in preeclampsia. Additional validation reports of these devices for the use in preeclampsia would be recommended.

Home blood pressure monitoring in a pregnant population with (a high risk of) hypertensive disease is being used to detect hypertension in pregnancy, to evaluate the effects of the start or alterations of antihypertensive medication and to improve hypertension control with thresholds up to 160 systolic BP and 100 diastolic BP. As values exceed these thresholds, clinical evaluation is essential in order to assess symptoms of hypertensive disease and review changes in kidney and liver function as well as effects on the fetus. The use of the iHealth Track and Omron HEM-9210T is unlikely to prevent or postpone the onset of severe hypertension or preeclampsia, but may contribute to earlier detection, better BP control, reduction of burden and costs of hospital visits and admissions and greater patient satisfaction. Previous validation studies in preeclampsia patients of recent years show contrasting results. The Microlife 3BTO-A is validated for use in pregnancy complicated with preeclampsia but failed to pass the criteria of the International Protocol in a following study by Nouwen et al. several years later.[18, 19] In the same report, the Omron M7 passed for diastolic BP in preeclampsia, but failed for systolic BP measurements in the same study group.

Strengths and limitations

While validated automated BP measuring devices for use in pregnancy are scarce, this study completed the validation trajectory of two devices of two different producers for use in pregnancy. This is a useful addition to the list of validated devices in pregnancy. Other strengths of this study include the use of an international standard protocol and the inclusion of pregnant patients both with and without preeclampsia. We chose to validate two monitors with Bluetooth functionality. In order to enhance maintenance and persistence of self-monitoring during pregnancy, we think easy connectivity with a smartphone is essential for telemonitoring. As there are no positive validation reports of devices with this function, to the best of our knowledge, these two monitors are now the first to be used by pregnant women.

Although we tried to follow the EHS validation protocol to full extent as prescribed, we were not able to use mercury sphymanometers. The use of mercury is no longer allowed in the Netherlands for safety reasons and they were replaced with calibrated aneroic sphygmanometers many years ago. The study group consisted of inpatients, hospitalized in pregnancy due to different complications. We cannot ascertain that the measurements from admitted patients would correspond with self measurements at home, in a less controlled setting. The ESH protocol advises the subjects to rest for 10-15 minutes in upright position to start validating in a rested state. In telemonitoring instructions, patients at home are also advised to rest prior to BP measurement. The use of antihypertensive medication in a number of subjects could have possibly reduced variability in BP.

Clinical implications

Potential advantages of the use of home blood pressure monitoring in pregnancy include the exclusion of the 'white coat effect', improvement of patient empowerment, reduction of outdoor patient clinic visits and the ability of (more) frequent monitoring with less interference with daily life. Women of reproductive age are frequent users of Internet, smartphones and applications.[20] The introduction of automated BP devices with Bluetooth connectivity facilitates the pathway of telemonitoring of blood pressure and other maternal parameters as weight, heart rate, dietary intake or symptoms of hypertensive disease. After synchronization of BP values with their own customized smartphone application, this can be shared with health care providers in special telemonitoring units on a daily basis. Prenatal care is integrating mobile technology more and more in order to offer personalized pathways after individual risk stratification. The validation of these two Bluetooth connected automated BP monitors may contribute to remote monitoring in perinatal care.

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CHAPTER 4

SAFE@HOME– FEASIBILITY STUDY OF A TELEMONITORING PLATFORM COMBINING BLOOD PRESSURE AND PREECLAMPSIA SYMPTOMS IN PREGNANCY CARE

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ABSTRACT

Objective

To study the feasibility of a telemonitoring platform for hypertensive disease in pregnancy, consisting of a wireless blood pressure monitor and an app in combination with an integrated preeclampsia symptom checklist.

Study design

Prospective observational study with 14 pregnant women during a 15 weekday study period. For feasibility purposes, compliance was measured by evaluating the number of entered BP and symptom checklists. Comparing all the entered values with the threshold values checked the accuracy of the automatic alerts. Usability and patient satisfaction were measured using questionnaires.

Results

Compliance rates for blood pressure and symptom checklist were 93% and 85% respectively. No false positive or missing alerts were found in the alarm system. The telemonitoring system alarmed 7 times for BP thresholds (3.8% of all received values), Of 167 returned symptom checklists, 93% of symptom alarms could be handled with expectant management because of concurrent normal blood pressure. The majority of participants were satisfied with the system.

Conclusions

This is the first feasibility study of a telemonitoring platform, combining remote monitoring of BP with preeclampsia symptoms in pregnancy care. Action from health care providers during telemonitoring is only needed in case of alarming combinations of results. This system is potentially very useful in care for women at risk for hypertensive disorders during pregnancy.

INTRODUCTION

In pregnancies considered at high risk for hypertensive complications, frequent outpatient visits are recommended to monitor maternal and fetal wellbeing.[1] Risk groups include women with chronic hypertension, preeclampsia or fetal growth restriction in a prior pregnancy, obesity, diabetes, or renal and cardiac disease. Prenatal appointments can range from visits every two weeks up to 1-4 times a week. During these visits, the focus is on blood pressure (BP), symptoms, weight, urine or blood analysis and fetal heartrate. Recurrent visits, either planned or unplanned, interfere with daily life and can be burdensome for the pregnant patient and her support system but also pose a substantial burden to perinatal care resources. [2]

Young women, in their reproductive years, are frequent users of Internet, social media and smartphone apps.[3] Home monitoring or telemonitoring of BP self-measurements could be a possible solution to improve care satisfaction while achieving more cost-effective care. American guidelines now recommend home monitoring for patients with chronic hypertension and gestational hypertension.[4,5] Contrarily, different guidelines regarding preeclampsia caution against automated blood pressure measuring devices for diagnosis and treatment threshold of preeclampsia, because both overestimation and underestimation of BP can occur in comparison with auscultatory measurements. [1,5] Pregnant women are willing to undertake repeated self-measurements and are able to record blood pressure accurately.[6] Self-monitoring is more acceptable to pregnant women than frequent clinic visits and over 98% of women with hypertension in pregnancy reported they liked to be involved in their blood pressure management.[7]

Despite this evidence on self-measurement of BP in pregnancy, there is little information on the use of a platform that allows for repeated BP measures in combination with symptom reporting. Therefore, we developed a telemonitoring platform for BP monitoring in antenatal care with an integrated preeclampsia symptom checklist. The aim of this study is to examine the patient acceptability of telemonitoring using the app and BP monitor and to review the internal infrastructure to survey all observed measurements. In this feasibility study, the patient compliance, the efficacy of the automatic alert system, the usability and patient satisfaction of this novel telemonitoring strategy is examined.

METHODS

Recruitment

In June 2017, low-risk pregnant women at the outpatient clinic of the University Medical Center Utrecht Birth Center (The Netherlands), were asked to participate in this prospective observational study. Women between 18 and 40 years old with a gestational age < 34 weeks were eligible if they did not meet any of the following exclusion criteria: chronic hypertension, hypertensive disorder in a prior pregnancy, cardiac or renal pathology, obesity (BMI> 35),

or arm circumference> 42 cm. Participants were only included if they could read and speak the Dutch language and had access to a smartphone or tablet with internet connection. This study was exempted from approval of the Medical Ethics Committee of the University Medical Center in Utrecht (reference number 17/424), as the Committee confirmed that the Dutch Medical Research Involving Human Subjects Act (WMO) did not apply to this study.

The telemonitoring platform

After providing informed consent for the study, the subjects were granted access to the secured platform. The Luscii platform (by Focuscura, The Netherlands in collaboration with UMC Utrecht) is accessible through an app for iOS and also through a secured portal in a browser on any device (smartphone, tablet, computer). It contains an educational page with patient information on hypertension in pregnancy and hospital-specific contact information. Subjects were trained to obtain correct measurements with the iHealth Track, an automated non-invasive oscillometric device which has been validated for use in pregnancy.8 Automatically transferred to the app through Bluetooth, single measurements can be checked and sent to the platform's dashboard and trend graph. Written instructions on how to measure and use the app were provided at study start.

Figure 1: Impressions of the Luscii cVitals app for use in prenatal care. Left: Actions screen of the app with buttons to measure vital signs and to fill out the symptom score list. Right: in the Measurements screen of the app participants can review their own data visualized in trend graphs.

Table 1. The ten-question preeclampsia symptom checklist in the telemonitoring platform, to be answered with Yes or No buttons.

Do you have headaches?
Do you have visual problems?
Do you have a tight, band-like feeling around the upper stomach?
Do you experience severe upper abdominal pain?
Do your fingers feel numb?
Do you feel nauseous?
Do you have ankle, hand or face swelling?
Do you have contractions?
Do you have vaginal fluid loss?
Do you have vaginal bleeding?

In addition to blood pressure, data is also collected with the use of an in-app symptom checklist. This checklist contains 10 yes/no questions based on symptoms that occur in (the development of) hypertensive conditions as well as general pregnancy symptoms to continue to pay attention to pregnancy as a whole (Table 1). Both types of symptoms were included in the app to ensure pregnant participants could report all pregnancy-related symptoms from home for safety reasons. After uploading, the measurements are visible for both the patient (in the app, Figure 1) and the health care provider (in the existing electronic patient file).

Participants were asked to submit their BP and symptom checklist for three consecutive weeks on Monday to Friday before 10.00 AM, resulting in a study period of 15 telemonitoring days in total. Standard daily alerts (push notifications) were sent at 7.00 AM to ask to start their measurements.

Values exceeding the set threshold values led to alerts on the monitoring dashboard for health care providers. The acquired data was reviewed by an obstetric care professional [SK] every weekday at 10.30 AM. In this normotensive study population, BP alerts were set for a systolic value of >140 mmHg or diastolic >90 mmHg and / or an increase of 20 mmHg compared to the previous measurement. These thresholds were chosen as they indicate new-onset of gestational hypertension following international consensus, but all values can be altered in the dashboard to provide individual care.[9-11] The system was set to alert for the symptom checklist if 1 or more of the 10 questions was answered as a present symptom (Table 2). The alerts were reviewed with a protocol taking into account several combinations of hypertension and symptoms. If needed, the researcher would consult the obstetrician and subsequently contact the participant to advice one of the following: 1) expectant management or 2) same-day clinical assessment of blood pressure and symptoms and 3) if necessary with blood and urine analysis. To ensure patient safety, all alerts in the dashboard had to be switched off manually after processing the protocolled steps.

Table 2. Set standard threshold values for alarms in the telemonitoring platform. All thresholds are adjustable for each individual patient.

Parameter	Threshold	Alarm color in dashboard
Blood pressure		
	Systolic >140 mmHg	Orange
	Systolic >150 mmHg	Red
	Diastolic >90 mmHg	Orange
	Diastolic >100 mmHg	Red
	Increase (jump) > 20 mmHg	Red
Symptom checklist		
	1 or more present symptoms	Red

Outcome measurements

Patient interaction and compliance was measured by registering the number of times patients sent their blood pressure and/or the checklist. The accuracy of the automatic alert system was evaluated by manual comparison of all entered values with the system thresholds for error positive or missing alerts. Clinical impact of the alert system could be assessed through the submitted combination of BP and concurrent presence or absence of preeclampsia symptoms. The patient satisfaction and usability of the app and platform was examined one week after the end of the study period. The online survey contained 8 statements with 5 answer options (varying from strongly agree to strongly disagree), 3 questions using a 10-point Likert scale and an open comment form.

RESULTS

Participants

In June 2017 a total of 14 pregnant women were included, after counseling of 33 women. Baseline characteristics of the study population are represented in Table 3. Ten participants used an iOS device and downloaded the app to send their measurements (71%), four used an Android device and manually entered the data in the web-based portal.

During the first 4 telemonitoring days, one participant sent in multiple measurements exceeding the set threshold (BP of >140/>90) at 14 weeks gestational age, despite baseline check of in- and exclusion criteria. The measurements were confirmed in the outpatient clinic and she was diagnosed with chronic hypertension. Because the telemonitoring platform was able to detect this development of disease, her pregnancy was followed up (including medication) outside our study protocol. Therefore, this participants' data on interaction and experiences was excluded, leaving 13 out of 14 participants for final data analysis.

Table 3. Maternal characteristics (total n=14).

Characteristic	
Age, mean (SD)	30.3 (3.10)
Pre-pregnancy BMI (kg/m^2), mean (SD)	23.0 (3.35)
Gestational age, weeks (range)	21.2 (10+1 – 32+4)
Nulliparae, n (%)	7 (50)
Educational Level, n (%)	
Unknown	2 (14)
Secondary education	3 (22)
Post-secondary education	9 (64)
Medical history, n (%)	
Inflammatory bowel disease	1 (8)
Urolithiasis	1 (8)
Depression	1 (8)
Prior pregnancy complications, n (%)	
Ectopic pregnancy	1 (8)
Placenta praevia	1 (8)

Legend: BMI, body mass index; SD, standard deviation

Table 4; Participant interaction and compliance during the 15- day study period (aimed number of sent data = 15 for both BP and symptoms). (BP, blood pressure)

Subject Number	**Blood pressure (sent)**	**Blood pressure (aimed)**	**Rate of BP compliance**	**Symptom checklist (sent)**	**Symptom checklist (aimed)**	**Rate of checklist compliance**
S01	16	15	> 100 %	16	15	> 100 %
S02	16	15	> 100 %	16	15	> 100 %
S03	17	15	> 100 %	4	15	27 %
S04	17	15	> 100 %	16	15	> 100 %
S05	12	15	80 %	11	15	73 %
S06	6	15	40 %	6	15	40 %
S07	15	15	100 %	15	15	100 %
S08	16	15	> 100 %	15	15	100 %
S09	8	15	53 %	10	15	67 %
S10[a]	stopped			stopped		
S11	15	15	100 %	13	15	88 %
S12	16	15	> 100 %	17	15	> 100 %
S13	16	15	> 100 %	16	15	> 100 %
S14	12	15	80 %	12	15	80 %
Total	182			167		
Mean	14	15	93 %	12.8	15	85 %

Legend: BP: blood pressure

[a]Participant S10 was diagnosed with hypertensive disease with help of the telemonitoring platform and subsequently stopped the study prematurely

Participant interaction and compliance

During the 15 weekday study period, the 13 participants who completed the study sent in their BP and symptom checklist on average, respectively, 14.0 and 12.8 times. The total compliance rate, as shown in Table 4, was 93% for blood pressure and 85% for symptom checklist uploads.

Seven participants (54%) provided us with more data than requested, resulting in compliance rates (theoretically) above 100%. One of them also uploaded data during Saturday and Sunday, despite our study guidelines only to measure during weekdays.

Two participants (S06 and S09) showed a clearly lower compliance rate (less than 55%) compared to the rest of the group. One participant noted she did not feel the urge to measure on a daily basis, as she was not experiencing symptoms or high blood pressure during the study period. The other participant did not mention a reason for lower compliance.

The accuracy of the automatic alert system

In the BP alarm system 7 alerts occurred (3.8% of all 182 BP measurements). In 4 of these 7 alarms, the upper threshold for either systolic or diastolic BP was exceeded. These 4 alerts were all sent by the one participant (S10) who was subsequently diagnosed with chronic hypertension.

The other three alerts appeared because of an increase of more than 20 mmHg in either systolic or diastolic pressure compared to the previous measurement. These accidental rises of blood pressure could be handled with expectant management after reviewing the BP trend and/or the absence of preeclampsia symptoms, as could be directly reviewed in the adjacent checklist.

After reviewing all variables of the seven BP alerts, no false positive alerts were found. Subsequent manual comparison of all other received values with our set thresholds detected no missing or incorrect alerts (Table 5).

In 15 days, 167 symptom checklists were uploaded, of which 73 (43.7%) alarmed because of present symptoms. Frequently, participants reported multiple symptoms in the same checklist. This resulted in a total of 111 symptoms in 73 separate alarms for the checklists, reporting at least one symptom at a time. Braxton-Hicks contractions (42x, 37.8%) and peripheral edema (29x, 26.1%) were the most common reported symptoms (Figure S2). Out of all 167 received symptom checklists, 5 (3.0%) resulted in the advice to consult a health care provider. Reasons for referral included an episode of vaginal blood loss or a combination of hypertension and symptoms. Combinations of a positive symptom checklist in normotensive participants were handled with expectant management, as per protocol.

Table 5. Accuracy of the BP telemonitoring platform alarm system. (BP, blood pressure)

	Alarm type	n (%)	After manual check	Clinical impact
Total BP submitted		186		
BP alarms	Exceeded threshold	4 (2.1%)	No false positive alarms	Diagnosis of chronic hypertension in 1 participant
	20 mmHg raise	3 (1.7%)	No false positive alarms	Because of absence of preeclampsia symptoms; expectant management
	No BP alarms	179 (96.2%)	No false negative alarms	

Participant experience

Participants reported that the provided instructions about the use of the monitor and the elements of the app were clear and that the BP monitor was easy to use. Only 1 woman requested additional explanation on the second day of the study.. It took the participants 2-5 minutes a day (mean 3.4 minutes) to take measurements and reply to the checklist in the app or the web portal. The usability of the BP monitor is rated an average of 8.9 on a 1-10 scale (range 8-10), the app/web portal 7.6 (range 5-10) and the content of the app 8.0 (range 7-10). Two participants reported that the web portal used by Android users was not considered user-friendly, as the design of the webpage was not suitable for their screen. Not all participants (3 out of 10 iOS users) managed to connect the iHealth monitor to the iOS app with Bluetooth. After referral to the Luscii helpdesk, technical issues could be fixed. The platform was considered useful to gain more insight in BP trend (77%, 10/13), to feel involved in prenatal care (85%, 11/13) and to feel engaged in care participation (77%, 10/13) (Figure S3). The majority of participants (12/13) strongly agreed to the statement "I would use the telemonitoring platform if there would be a reason for frequent monitoring". All participants (13/13) would recommend telemonitoring by the blood pressure monitor and the Luscii app to other patients. No differences were found in the results of users of iOS users versus Android users.

Research team evaluation

From the perinatal care professional point of view, all stages of the feasibility trial were discussed to evaluate the concept of the telemonitoring strategy and to improve it for further implementation. The medical professionals stated the dashboard was clear with easy reviewing of alarms, due to the connection with our hospitals' electronic health record. In some cases of alerts, the participants were contacted by telephone. The patients appreciated this extra form of attention, information and reassurance. Additional patient instructions about when to measure and when not to measure (e.g. outside office hours or in case of subacute onset of symptoms) was found an essential aspect of the strategy and to assure patient safety in a high risk population.

DISCUSSION

This telemonitoring platform, with the feature to combine repeated BP measurements with associated preeclampsia symptom alerts, was found feasible for pregnancy care in the outpatient clinic. Compliance rate of participant interaction in the study period proved to be favourable with nearly 85% of the participants completing most of the daily measurements. The alert system was accurate and the novelty to report symptoms in an in-app questionnaire demonstrated to be of additional clinical value: incidental BP peaks without the presence of any preeclampsia symptoms could be handled with expectant management without extra in-hospital or phone consultations. The participants were content with the app and BP monitor and would recommend it to other patients. The 3-5 minute measurement activity did not interfere with daily activities. Participants reported favourable usability of the telemonitoring system and affirmed the usefulness for higher patient engagement in prenatal care.
For patient safety it is strongly recommended to only use BP monitors that have been validated for use in pregnancy according to international consensus guidelines.[12] The iHealth Track used in this study has been validated in a pregnant population with and without preeclampsia.[8]

Previous retrospective and prospective studies have used BP telemonitoring with weekly home measurements during the full course of pregnancy, or after diagnosis of (suspected) hypertension.[10,13-15] Their results confirm the acceptability and feasibility of telemonitoring and report a reduction of clinic visits without adverse perinatal effects. As social changes are demanding a shift to home-based care, both patients and care provides are embracing telemedicine for its usability, tendency to improve access to care, communication and outcomes while decreasing clinic visits and travel time.[16] This shift is assumed to have profound cost-saving effects in favor of telemonitoring, an important aspect regarding the ever-increasing health care costs – and workloads.[17] Enrolment of >2000 participants in the Pregnancy ResearchKit app in the United States showed high patient engagement of remote monitoring of maternal parameters (>100,000 measurements) and filling out surveys (>14,000) in a 9 months study period. The combination of patient education (using the WebMD Pregnancy app) and the visualization of personal data will help pregnant women to understand and interpret healthy behaviour and risks, adding to informed medical decision making.[18] Our use of both BP and pregnancy-related symptom collection is not described before in previous studies and may help preventing overconsumption as both objective (BP) home measurements are combined with subjective symptom reporting.

This feasibility study was set up for uncomplicated pregnancies to test the use of technical devices and hospital logistics with the use of our telemonitoring platform. The study period comprised a maximum of 15 consecutive weekdays, as we did not want to impose daily

measurements for a longer period to a healthy pregnant population. However, the future target population will consist of women with increased risk for hypertensive disorders in pregnancy. The observed participation grade and compliance rate might improve when the system is used for high risk women, with an actual increased risk for hypertension as an incentive for self monitoring. One participant met all inclusion criteria but was diagnosed with chronic hypertension during the study period. The use of the platform was thus beneficial in the early detection of new onset of hypertensive disease, which is one of the conceptual advantages of repeated remote monitoring in pregnancy. The other, healthy, participants had a high educational level which could have biased the results.

Our study shows that many alerts of symptoms occurred without immediate need for further action, after reviewing the combination of symptoms with the up-to-date BP. This is one of the conclusions that proved to be very useful for our evaluation of the system. Future telemonitoring in prenatal care could make use of the symptom checklist. However, from the results of our study, we conclude that in terms of usability, the standard symptom checklist should only be uploaded during periods of hypertension (of BP >140 / >90 mmHg) or accidental raises in BP. Depending on the intended use of the platform, questions about general pregnancy symptoms could wither be excluded or made optional for future research or implementation. Individual protocols for timing and frequency of remote monitoring can be developed after risk stratification within specific groups of pregnancy complications or comorbidities. To assure patient safety, patient instructions should always include the need to call the clinic in case of emerging symptoms outside office hours. Recommendations for further research include updated versions of patient instructions (to obtain correct measurements and to enhance compliance rates) and updated protocols and flowcharts (for alarm evaluation for our telemonitoring team). In future implementation of this strategy, several routes of patient-clinician-communication are possible. In our centre, in this feasibility study, we chose to place a care provider for triage between patient and physician. In a different approach, it is also possible to train physicians how to review alerts themselves and communicate with patients based on the daily observed measurements. However, if telemonitoring is implemented to study the use of health care resources or cost-effectiveness, organizations may benefit from a task shift from physician to specialized nurse of midwife regarding the home monitoring or alert reviewing, under the supervision of a gynaecologist. Future trials should investigate the effects of the platform on perinatal outcomes, patient experiences and cost-effectiveness, as well as the opinion of health care providers.

This feasibility study in uncomplicated pregnancy shows that a digital platform with telemonitoring of blood pressure self-measurements and symptom scores can be used in pregnancy care. While reassuring results from home do not appear in the daily alarm system, action from health care providers during remote monitoring is only needed in case of alarming results. The possibility to monitor the combination of BP values with preeclampsia

symptoms using a smartphone application holds the promise to improve outpatient care for women at risk of hypertensive pregnancy disorders.

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Supplemental Material

Figure S1. Results from the 10-question symptom checklist. Total number of reported symptoms is 111, of which Braxton-Hicks contractions and peripheral edema were most described.

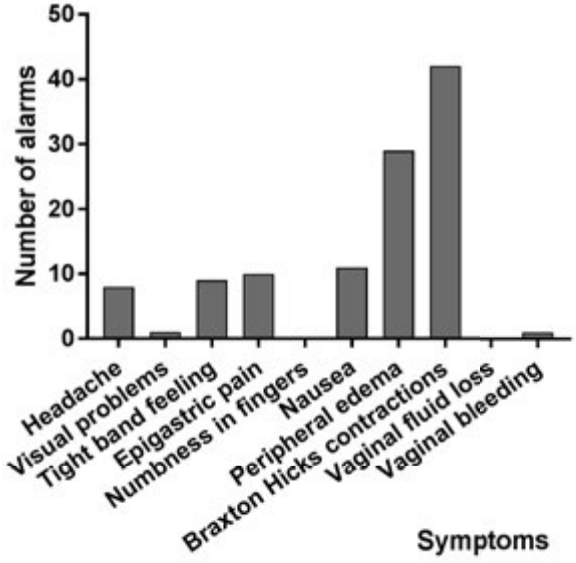
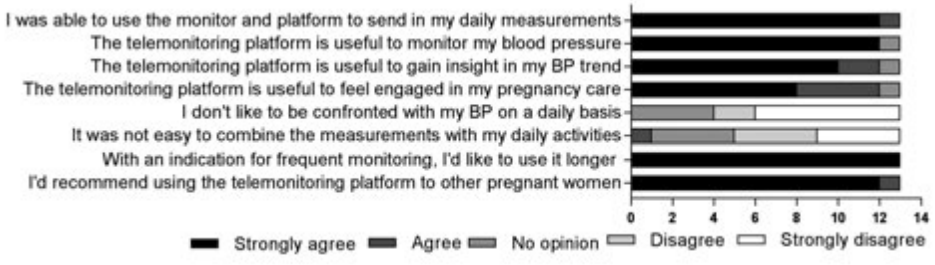


Figure S2: Plot of qualitative survey on the (use of) the telemonitoring platform (n=13)



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CHAPTER 5

SAFE@HOME: DIGITAL HEALTH PLATFORM FACILITATING A NEW CARE PATH FOR WOMEN AT INCREASED RISK OF PREECLAMPSIA – A CASE-CONTROL STUDY

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ABSTRACT

Objective
In women at risk of developing preeclampsia, we evaluated the use of a digital health platform for telemonitoring blood pressure and symptoms combined with a minimal antenatal visit schedule.

Study design
A case-control study for women with chronic hypertension, history of preeclampsia, or maternal cardiac or kidney disease. A care path was designed with reduced visits enhanced with a digital platform (SAFE@HOME) for daily blood pressure and symptom monitoring starting from 16 weeks of gestation. Home-measurements were monitored in-hospital by obstetric professionals, taking actions upon alarming results. This prospective SAFE@HOME group was compared to a retrospective control group managed without self-monitoring.

Main outcome measures
Primary: healthcare consumption (number of antenatal visits, ultrasounds, admissions and diagnostics), user experiences of the platform.
Secondary: maternal and perinatal outcomes.

Results
Baseline characteristics of the SAFE@HOME (n=103) and control group (n=133) were comparable. In the SAFE@HOME group, antenatal visits (mean 13.7 vs 16.0, $p<0.001$) and ultrasounds (6.3 vs 7.4, $p=0.005$) were lower compared to the control group. Admissions for hypertension or suspected preeclampsia were significantly fewer in the SAFE@HOME group (2.9% versus 13.5%, $p=0.004$). Telemonitoring participants were highly satisfied using the platform. No differences were observed for maternal and perinatal outcomes.

Conclusions
Our care path including blood pressure telemonitoring for women at risk of preeclampsia allows fewer antenatal visits, ultrasounds and hypertension-related admissions. We observed no differences in perinatal outcomes. These results suggest that telemonitoring of blood pressure is feasible in a high-risk pregnant population and has the potential to profoundly change antenatal care.

INTRODUCTION

Hypertension in pregnancy is increasingly common, and an important cause of maternal and neonatal morbidity and mortality, at short as well as long term.[1,2] Frequent monitoring of blood pressure (BP), fetal growth, blood and urine during pregnancy is recommended to early identify and monitor hypertensive disease.[3] Interfering with daily life, (un)planned visits and hospitalization pose a substantial burden to patients and care resources.[4]

International guidelines from 2013 onwards recommend self-measurements for patients with (gestational) hypertension.[5-7] Recent research has shown that pregnant women are willing to undertake repeated self-measurements for involvement of blood pressure management.[8-10] As such, the adoption of digital health has been suggested to achieve higher-value antenatal care.[11]

We developed a digital telemonitoring platform enabling home blood pressure measurements and preeclampsia symptom reporting.[12] This redesign of antenatal care, with a predefined minimal visit schedule and telemonitoring, is anticipated to enhance digital interaction and women's autonomy while maintaining safety of antenatal care. Furthermore, telemonitoring might allow less frequent antenatal visits. It could potentially also lead to more visits as a result of an overload of data or questions in contrast. The precise role of digital exchange of home measurements in pregnancies at increased risk has yet to be established.

We evaluated our digital health platform in antenatal care for patients at increased risk of developing preeclampsia, together with a newly developed reduced antenatal visit schedule, from 16 weeks gestational age onwards.

METHODS

Study population and design

This case-control study was conducted in two perinatal centres in urban areas in the Netherlands: one university hospital (2500 deliveries annually, both secondary and tertiary care) and one general teaching hospital (3000 deliveries annually). The study population consisted pregnant women with a singleton pregnancy and one (or more) of the following risk factors for preeclampsia: chronic hypertension, preeclampsia in a prior pregnancy, maternal cardiac disease, or maternal kidney disease. A prospective group of women, managed with use of the digital platform, was compared with a retrospective group with identical risk factors at start of pregnancy, but managed with conventional care. This study was submitted to the Medical Ethics Committee of the University Medical Center in Utrecht (17/424). The committee judged that the Dutch Medical Research Involving Human Subjects Act (WMO) did not apply to this study.

The SAFE@HOME group consisted of women, who presented with one of the fore-mentioned risk factors between October 2017 and December 2018 in our clinics. Eligible candidates for the prospective study were >18 years of age, had access to a smartphone or tablet with Internet connection and could understand Dutch or English language. Kidney transplant patients and arm circumference >42 cm (as prescribed by the instructions of the monitor) were considered an exclusion criterion.

The control group consisted of retrospectively selected women with one of the aforementioned four risk factors at start of pregnancy. After database search for these risk factors amongst all deliveries between 1-1-2015 and 31-12-2016, patients were included in this control group only if they received antenatal care from intake to delivery in the same centre. Exclusion criteria were maternal age <18 years and kidney transplant. Antenatal care in the control group was based on the Dutch guideline on hypertensive disorders of pregnancy, without use of home blood pressure measurements.[13] Follow-up visits were planned once per two weeks, with increased frequency if indicated by their care provider, depending on the patient's condition, BP or medication use. Antihypertensive medication was generally prescribed in case of blood pressure >160/>110 mmHg. Hospitalization was recommended in case of preeclampsia, or fetal growth restriction with indication for daily cardiotocography (pulsatility index of the umbilical artery >95th centile).

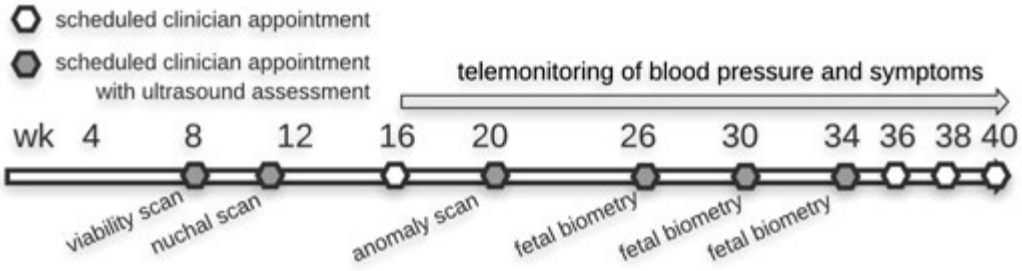
Intervention

The digital health platform consisted of the Luscii platform (by Focuscura, the Netherlands, in collaboration with UMC Utrecht) and the iHealth Track automated blood pressure monitor, validated for use in pregnancy.[14]

Development of the platform was described before and its use was found feasible in our hospital setting in a low risk pregnant population.[12] This study showed good participant compliance and high accuracy of the alarm system. [12] Subsequently, telemonitoring with the platform was offered to patients at risk of preeclampsia from October 2017 onwards. As part of this novel strategy, a uniform care path was predefined (Figure 1). We organized 4 multidisciplinary meetings with obstetricians, internists, cardiologists and nephrologists, nurses and patients for the development of the schedule. Considering the home-measurements and symptom scores, they discussed the desired structure of care, outcome measures of interest and the objective of each planned clinic and ultrasound visit.

Before start of the study, a local telemonitoring team was set up. Nurses and midwives of these teams were trained in a 1-h course to 1) register and instruct new participants to use the monitor and platform and 2) perform daily monitoring of alerts and subsequent actions. Obstetricians (in training) were trained how to access the home measurements and to plan future appointments using the predefined schedule.

Figure 1. Predefined antenatal visit schedule as part of the intervention for patients at risk of development of preeclampsia



Women who gave written informed consent were provided access to the secured platform from 16 weeks gestational age onwards. They were trained to obtain correct measurements with the iHealth Track. From study enrolment to delivery date, they were asked to submit a single blood pressure on weekdays before 10.00AM. In-app or email reminders were sent automatically at 7.00AM. The blood pressure measurement was transferred to the app with Bluetooth, and the pregnant woman could forward it to the platform after manual check. If blood pressure was raised, participants answered an in-app symptom checklist, containing 10 yes/no questions for symptoms that occur in (the development of) preeclampsia as well as general pregnancy symptoms (Table 1). Uploaded values were visible for both the patient and the healthcare provider, on a monitoring dashboard in the electronic health record.

Values exceeding the set threshold values led to alerts on the monitoring dashboard, reviewed by a member of the telemonitoring team every weekday at 10.30 AM. Alerts were set for a systolic value of >140 mmHg or diastolic >90 mmHg and/or an increase of 20 mmHg compared to the previous measurement. These thresholds were chosen as they indicate new-onset of gestational hypertension following international consensus, but can be altered in the dashboard to provide individual care. [15-17] For the symptom checklist, the platform alarmed if ≥1 symptoms were present. Alerts were reviewed with a protocol of flowcharts taking into account several combinations of hypertension and symptoms (Supplemental Figure 1). If needed, the telemonitoring team would consult the obstetrician and subsequently contact the participant to advice one of the following: 1) expectant management or 2) same-day clinical assessment of blood pressure and symptoms and 3) if necessary with blood/urine analysis, 4) adjustment of antihypertensive therapy, 5) admission to the antenatal ward, and 6) induction of labour. To ensure patient safety, all alerts in the dashboard had to be switched off manually after processing the protocolled steps.
In both study groups therapeutic interventions including induction of labour or caesarean section were started according to local protocol based on the Dutch national guideline.[13]

Table 1. The ten-question preeclampsia symptom checklist in the telemonitoring platform, to be answered with Yes or No buttons.

Do you have headaches?
Do you have visual problems?
Do you have a tight, band-like feeling around the upper stomach?
Do you experience severe upper abdominal pain?
Do your fingers feel numb?
Do you feel nauseous?
Do you have ankle, hand or face swelling?
Do you have contractions?
Do you have vaginal fluid loss?
Do you have vaginal bleeding?

Outcomes and data collection

Primary outcomes were healthcare consumption and user experiences of the digital telemonitoring platform. Secondary outcomes were maternal and neonatal perinatal outcomes.

For healthcare consumption, the number of antenatal visits, ultrasounds for fetal assessment, blood and urinary analysis, medication use and admissions were extracted from participants' hospital system.

For user experiences, SAFE@HOME participants were invited to answer an online survey at 36 weeks of gestation with 10 statements regarding their experiences with the platform on a 5-point Likert scale. Derived from the Luscii webportal, the start, duration and frequency blood pressure and symptom monitoring, as well as number of alerts and raised readings were recorded.

For maternal and perinatal outcome, pregnancy and delivery data were recorded and used to compare both groups. Risk factors for preeclampsia in each group and other maternal characteristics were collected at baseline from hospital records. Chronic hypertension, gestational hypertension, preeclampsia and eclampsia were defined according to ISSHP criteria.[15]

Statistical analyses

Given the exploratory nature of this study, no formal sample size calculation was performed. Continuous outcome variables were represented as means with standard deviations or, if skewed, medians with interquartile ranges (IQR), and were compared by the Student's t-test or Mann-Whitney-U test. Categorical outcome variables were compared between groups by the chi-square or Fisher's exact test. P-values below 0.05 were considered as statistically significant. Statistical analysis was performed with IBM SPSS version 25.

RESULTS

For the SAFE@HOME group, 111 women were found eligible and invited to participate, of which 109 consented (Figure 2). During the study period, 2 participants experienced pregnancy loss <21 weeks of gestation, and 2 were lost to follow-up. Only 2 women (<2%) were excluded from the SAFE@HOME strategy and returned to standard care because they were non-compliant to study instructions. For the final analysis, 103 participants were included in in the SAFE@HOME group.
In the control group, 133 eligible women were included. Figure 3 shows the selection of these 133 participants from retrospective database search.

*Figure 2. Flow chart of participants enrolled in the **SAFE@HOME group***

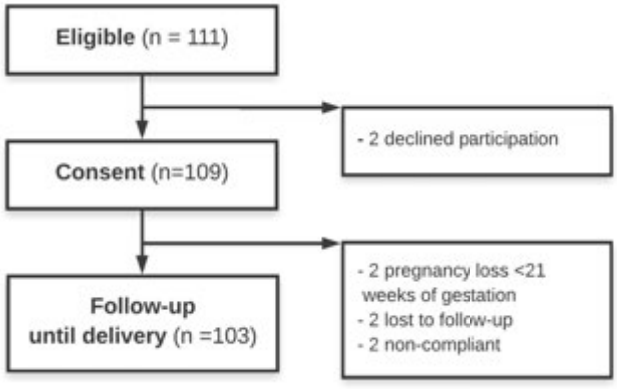


*Figure 3. Flow chart of participants enrolled in the **control group***

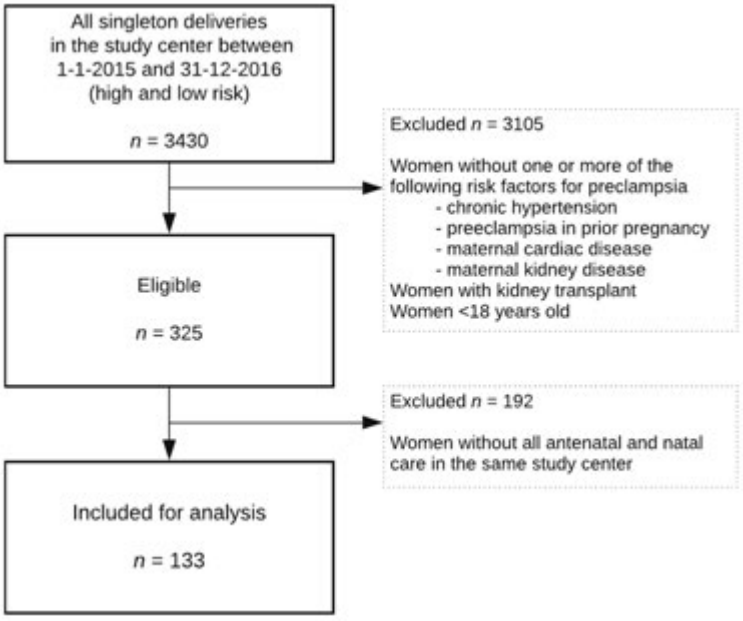


Table 2. Baseline characteristics

		SAFE@HOME n = 103	**Control n = 133**	**p-value**
Age (years)	mean (SD)	33.7 (4.6)	33.1 (4.7)	0.27
Body mass index (kg/m2)	mean (SD)	25.2 (4.5)	26.5 (5.75)	0.06
Ethnicity	n (%)			
Caucasian		82 (79.6)	97 (72.9)	0.23
Mediterranean		14 (13.6)	24 (18.0)	0.36
Afro–Caribbean		4 (3.9)	6 (4.5)	1,00
Other / unknown		3 (2.9)	6 (4.5)	0.74
Education	n (%)			
Primary school or less		3 (2.9)	2 (1.5)	0.66
High school		9 (8.7)	5 (3.8)	0.11
Secondary school		36 (35.0)	44 (33.1)	0.76
Professional education		30 (29.1)	48 (36.1)	0.26
University graduate		25 (24.3)	34 (25.6)	0.82
Nulliparity	n (%)	31 (30.1)	36 (27.1)	0.61
Smoker	n (%)	2 (2.0)	6 (4.6)	0.47
Psychiatric disorder in pregnancy	n (%)	7 (6.8)	8 (6.3)	0.84
Prior HDP	n (%)	40 (38.8)	68 (51.1)	0.13
Systolic BP at intake (mmHg)	mean (SD)	120 (16.9)	122 (17.8)	0.26
Diastolic BP at intake (mmHg)	mean (SD)	74 (12.3)	75 (12.8)	0.39
Risk factor for inclusion	n (%)			
Prior preeclampsia		23 (22.3)	44 (33.1)	0.07
Chronic hypertension		28 (27.2)	45 (33.8)	0.27
Cardiac disease *		35 (34.0)	38 (28.6)	0.37
Kidney disease §		17 (16.5)	6 (4.5)	0.002
Start of telemonitoring	Weeks of gestational age	17.9 (3.9)	-	-
Duration of telemonitoring	Weeks	20.2 (4.0)	-	-

Legend: BP, blood pressure; HDP hypertensive disorder of pregnancy; SD, standard deviation
** e.g. maternal congenital heart disease, arrhythmias, valvular heart disease, aortopathy*
§ e.g. (obstetric) antiphospholipid syndrome, systemic lupus erythematosus, chronic kidney disease

Baseline characteristics are shown in Table 2. Maternal age, BMI, ethnicity, education level and parity were similar between groups, as were history of hypertensive disorders of pregnancy (HDP) and intake blood pressure. The distribution of the four risk factors for preeclampsia, as reason for study inclusion, was comparable for preeclampsia in prior pregnancy, chronic hypertension and maternal cardiac disease. However, more women with kidney disease were included in the SAFE@HOME group (16.5% vs 4.5%, p = 0.002), as one of the study centres became a referral centre for kidney disease in pregnancy during the intervention period.

Healthcare consumption

Table 3 demonstrates healthcare consumption during pregnancy. The number of antenatal visits from the first visit to delivery was significantly lower in the SAFE@HOME group as compared to the control group (mean 13.7 [4.0] vs 16.0 [4.1], p <0.001). The total number of ultrasound assessments was also significantly lower in the SAFE@HOME group (mean 6.3 [2.7] vs 7.4 [2.9], p=0.005). These significant reductions were primarily observed between 34 weeks of gestation and delivery, which corresponds to the proposed visit schedule (Figure 1 and Table 4).

In the SAFE@HOME group, observational admissions for hypertension or diagnosis/ exclusion of suspected preeclampsia were significantly lower compared to the control group (2.9% vs 13.5% of participants, p=0.004, Table 2). Overall, no significant difference was found in the number of patients who needed an antenatal admission for any other obstetric indication (i.e. fetal monitoring, antepartum haemorrhage or intravenous treatment for severe hypertension or preeclampsia): 31.1% in SAFE@HOME vs 39.1% in control group, p=0.20. The mean number of blood tests for evaluation of hypertension/preeclampsia did not differ between groups.

Table 3. Results of healthcare consumption

		SAFE@HOME n = 103	**Control n = 133**	**p-value**
Total number of visits	mean (SD)	13.7 (4.0)	16,0 (4.1)	<0,001
GA 0-26 weeks	"	5.9 (2.5)	6.2 (2.4)	0.23
GA 26-34 weeks	"	4.1 (2.0)	4.5 (2.0)	0.16
GA 34- delivery	"	3.8 (2.0)	5.3 (2.4)	<0,001
Total number of ultrasound assessments	mean (SD)	6.3 (2.7)	7.4 (2.9)	0.005
GA 0-26 weeks	"	2.8 (1.5)	3.5 (1.5)	<0.001
GA 26-34 weeks	"	2.7 (1.6)	2.6 (1.7)	0.58
GA 34- delivery	"	0.9 (0.9)	1.1 (1.2)	0.004
≥ 1 antenatal admissions (for any obstetric indication)	n (%)	32 (31.1)	52 (39.1)	0.20
Duration (days)	median (IQR)	4.5 (2-11.5)	6 (2-19)	0.50
≥ 1 antenatal admissions for observation of hypertension or suspected preeclampsia	n (%)	3 (2.9)	18 (13.5)	0.004
Duration (days)	median (IQR)	2 (2-2)	2.75 (2-4)	0.10
Number of blood tests for hypertension evaluation	mean (SD)	2.9 (3.7)	2.5 (3.6)	0.38

Legend: GA, gestational age; PE, preeclampsia

User experiences and data on home measurements

The online survey on SAFE@HOME experiences was answered by 51 (49%) participants. Few had difficulties with using the system (4%, 2/51) and instructions regarding the use of the BP monitor and app were clear to almost all (96%, 49/51) (Supplemental Figure 2). Daily measurements took ≤5 minutes for 81% (mean 4.6 min), and 98% (50/51) could easily perform their routine tasks while using the platform. The vast majority was satisfied with the use of the app and platform (92%, 47/51) and especially parous participants would recommend it to other women (96.9% of multiparous vs. 73.7% of nulliparous women).

Telemonitoring participants started their home measurements on average at 17.9 weeks of gestation (SD 3.9) and continued this for 20.2 weeks (SD 4.0) until delivery (Table 2). During pregnancy, the median number of uploaded blood pressure measurements per participant was 90.0 in total (IQR 68.0-107.0, range 18-201) or 4.5 per week of telemonitoring (IQR 3.6-5.0, range 0.9 – 12). The median compliance rate for all scheduled blood pressure measurements was 91.2% (IQR 70-100, range 34 – 100).

Perinatal outcome

Table 4 shows the pregnancy outcomes in both groups. At delivery, diagnoses of gestational hypertension, preeclampsia, chronic hypertension without superimposed preeclampsia or normotensive pregnancy were similar between groups.

Approximately 20% of all participants developed preeclampsia, and fetal growth restriction (estimated fetal weight <10th centile) occurred in ±10% of all pregnancies (Table 3).

Labour induction was more frequent in the SAFE@HOME group (56.3 vs 38.3%, p=0.006). However, hypertension as the main indication for induction was not significantly different between groups (56.9 vs 54.9 % of inductions, p=0.99). Planned induction for patients with cardiac disease was more frequent, although not significant, in the SAFE@HOME group (16.5 vs 9.0%, p=0.08). No other differences were found regarding mode of delivery.

One antepartum fetal death, not related to telemonitoring, occurred in the SAFE@HOME group, in a woman included because of a history of preeclampsia. There were no maternal complications. No other serious adverse events were observed in both groups.

In general, no differences were detected in use of (iv) anti-hypertensive drugs, magnesium sulphate or glucocorticoids for fetal lung maturation (Table 4). Results were also similar for gestational age at delivery (mean 38.3 weeks (2.1) vs 38.8 weeks (2.3) p=0.11), birth weight <5th centile (4.9 vs 9.0 %, p=0.22), and admission to neonatal intensive care unit (1.9 vs 4.5 %, p= 0.47).

Table 4. Pregnancy outcomes

		SAFE@HOME n = 103	Control n = 133	p-value
Final maternal diagnosis of HDP in current pregnancy	n (%)			
Gestational hypertension		9 (8.7)	4 (3.0)	0.06
Preeclampsia		22 (21.4)	27 (20.3)	0.84
HELLP syndrome		1 (1.0)	0 (0)	0.44
Chronic hypertension without PE		23 (22.3)	26 (19.5)	0.60
No HDP (normotensive)		48 (46.6)	76 (57.1)	0.11
Suspected fetal growth restriction	n (%)	12 (11.7)	13 (9.8)	0.64
Glucocorticoid administration	n (%)	15 (14.6)	10 (7.5)	0.08
MgSO4 administration	n (%)	9 (8.7)	12 (9.0)	0.94
Use of anti-hypertensive drugs <20 w GA	n (%)	39 (37.9)	41 (30.8)	0.26
Use of anti-hypertensive drugs >20 w GA	n (%)	56 (54.4)	58 (43.6)	0.10
iv antihypertensive drugs ante-partum	n (%)	4 (3.9)	9 (6.8)	0.34
Iv antihypertensive drugs post-partum	n (%)	6 (5.8)	4 (3.0)	0.29
Mode of delivery				
Induction of labour	n (%)	58 (56.3)	51 (38.3)	0.006
*because of hypertension	n (%)	33 (56.9)	28 (54.9)	0.99
Primary caesarean section	n (%)	24 (23.3)	34 (25.6)	0.69
*because of hypertension	n (%)	7 (29.2)	12 (35.3)	0.62
Vaginal delivery	n (%)	61 (59.2)	72 (54.1)	0.43
Instrumental delivery	n (%)	9 (8.7)	6 (4.5%)	0.19
Secondary caesarean section	n (%)	9 (8.7)	21 (15.8)	0.11
Fetal/neonatal outcome				
GA at delivery (weeks)	mean (SD)	38.3 (2.1)	38.8 (2.3)	0.11
Birth weight (gram)	mean (SD)	3081 (638)	3203 (694)	0.17
Birth weight <5th percentile	n (%)	5 (4.9)	12 (9.0)	0.22
APGAR <7 at 5 minutes	n (%)	3 (2.9)	7 (5.3)	0.52
NICU admission	n (%)	2 (1.9)	6 (4.5)	0.47

Legend: GA, gestational age; HDP, hypertensive disorder of pregnancy; PE, preeclampsia

DISCUSSION

Main findings

We studied the use of a novel care path with telemonitoring of blood pressure and preeclampsia symptoms in a high-risk pregnant population. Our findings show that this strategy allows a reduced antenatal visit schedule, with fewer ultrasound assessments and antenatal hypertension-related admissions. However, evaluation was by comparison with a retrospective group without telemonitoring nor a fixed antenatal visit schedule. In our sample, no differences were found in adverse maternal or perinatal outcomes between the two strategies.

Comparison to the literature and interpretation

The NICE guideline on antenatal care recommends more frequent blood pressure monitoring for those at risk of HDP and several others mention self-monitoring as a useful addendum to antenatal care.[7,16] A recent individual patient data meta-analysis of 758 subjects found an insignificant difference between clinic readings and self-monitored blood pressure values.[17] Based on this evidence, our threshold for alerts was set at 140/90 mmHg to be of clinical importance.

Recent literature describes a variety of monitoring strategies for women with (a higher risk of) hypertension in pregnancy. [18-21] In general, reduction of antenatal visits with help of out-of-office self-measurements, as found in our study, are in line with several other studies. One retrospective study of blood pressure telemonitoring for diagnosed hypertension in pregnancy showed a reduction of antenatal visits and admissions.[18] Two case-control studies started blood pressure self-monitoring in women with diagnosed hypertension, without telemonitoring but providing written instructions to patients when to contact the hospital. [19,20] Starting self-monitoring at 30–36 weeks of gestation, fewer visits were required with self-monitoring compared to a retrospective group with traditional care, in both studies. More importantly, the shift from hospital to home care did not seem to negatively affect pregnancy outcomes, although study sample sizes were likely not large enough to determine this. [18-20] One other prospective study started telemonitoring at start of pregnancy but did not include a control group for comparison of results.[21] There is conflicting data on the rate of labour induction in the literature. As for our study, induction of labour was more frequently started in the SAFE@HOME group, however hypertension as the main reason for induction of labour was similar between groups.

Our study differed from the described studies on several points. Our population of women, at risk of preeclampsia but without complications in first trimester, started telemonitoring eary in pregnancy (mean 17.9 weeks of gestation) in stead of starting at 30-36 weeks. Also, a symptom checklist was included within the platform. This combination proved to

be beneficial for the full course of pregnancy. Absence of both hypertension and symptoms requires no further action, while symptoms in case of hypertension indicate need for evaluation.

Strengths and limitations

Our digital platform is one of the first to combine both blood pressure and symptom reporting, used with a reduced visit schedule. Prior to the study start, we validated the blood pressure monitor and carried out a feasibility study to test the Bluetooth-connected platform.[12,14] Eligible candidates were willing to participate in telemonitoring, which is reflected in the high consent rate. Only 2/109 participants were transferred to standard care because of non-compliance. A limitation of this study is the comparison to a retrospective control group, which is likely to have caused selection bias. The greater proportion of included women with kidney disease in the SAFE@HOME group adds to heterogeneity, because of the specific etiology of kidney disease as an increased risk factor for preeclampsia. This might limit generalizability of results.

Our study was not powered adequately to draw conclusions regarding adverse perinatal outcomes and therefore, future studies with substantial sample size would be needed.

Lastly, the studied strategy is a combination of both a digital health platform for remote monitoring and a reduced visit schedule. It is unknown whether the implementation of either of these components of the intervention individually would result in a similar effect on healthcare consumption and adverse outcomes.

Future implications

Our results imply that use of telemonitoring at home of blood pressure and preeclampsia symptoms in high risk pregnancies allows for fewer antenatal visits, notably after 34 weeks of gestation. The use of home measurements did not lead to an increase in health care consumption. Increased experience and compliance of obstetric care professionals to the new strategy may enhance the reduction of care use in the future.

Several implications of blood pressure telemonitoring in pregnancy still need evaluation. Before widespread use of telemonitoring, more evidence is needed from larger prospective studies. Studied groups should include both women at risk of hypertension or preeclampsia at start of pregnancy, as well as those with established gestational hypertension or mild preeclampsia.[22] Current knowledge gaps include the safety and impact of telemonitoring on (early) detection and/or prediction of complications as well as its effect on subsequent interventions as medication use and hypertension control, induction of labour, optimal administration of corticosteroids.

In general, digital health has the potential to have profound cost-saving effects because of the decline in visits, admissions, travel time, and work absence.[23] Women of reproductive age are interested in digital health, as shown by their frequent use of smartphones and

pregnancy apps.[24,25] In future digital health studies of in pregnancy, use of healthcare services should be assessed too. Alongside its medical effects, cost-effectiveness must be evaluated before implementation of digital health in pregnancy care. The latter may also contribute to reimbursement of digital care.[26,27]

Conclusion

Use of a digital health platform for blood pressure and symptom telemonitoring allows for fewer antenatal visits and ultrasound assessments in pregnancies at risk of preeclampsia. In this study there was no increase of adverse maternal and neonatal outcomes as compared to the control group. Larger prospective studies on telemonitoring in pregnancy are needed for evaluation of perinatal safety outcomes and cost-effectiveness.

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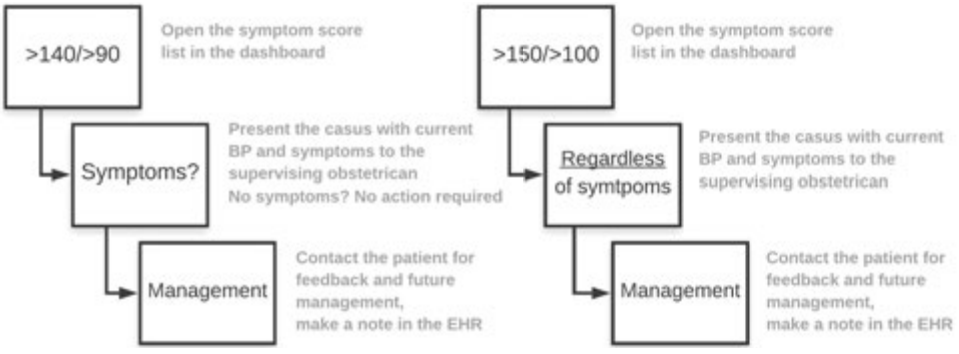
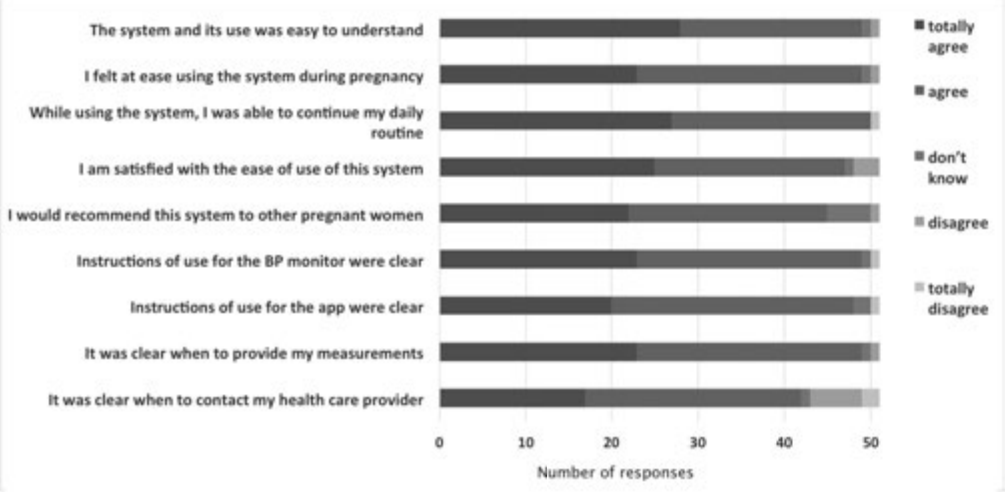
Supplemental material

Supplemental Figure 1. Flow charts to assist daily monitoring of home blood pressure measurements.



Supplemental Figure 2. Plot of the result of the user experiences questionnaires



CHAPTER 6

SAFE@HOME: COST ANALYSIS OF A NEW CARE PATHWAY INCLUDING A DIGITAL HEALTH PLATFORM FOR WOMEN AT INCREASED RISK OF PREECLAMPSIA

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ABSTRACT

Objective

To perform a cost analysis of the use of a new care pathway with a digital health platform for blood pressure telemonitoring for women at risk of preeclampsia.

Study design

This is a cost analysis of a case-control study with women with chronic hypertension, history of preeclampsia, maternal cardiac or kidney disease at intake of pregnancy. Antenatal care with a reduced visit schedule and a digital health platform (SAFE@HOME, n=97) was compared to a retrospective control group (n=133) with usual care without self-monitoring.

Main outcome measures

Costs per pregnancy (€) of healthcare consumption of antenatal clinic visits, ultrasound assessments, antenatal admissions, laboratory and other diagnostic tests, and societal costs such as traveling and work absence.

Results

Baseline characteristics and perinatal outcomes were similar between both groups. A significant reduction of antenatal visits, ultrasounds and hypertension-related admissions was associated with use of the digital platform. In the SAFE@HOME group, costs of antenatal care, including the costs of the digital platform, were 19.7% lower compared to the control group (median €3616 [IQR 3071 – 5329] vs €4504 [IQR 3515-6923], p=0.001). Total costs per pregnancy, including societal costs, were also reduced (€7485 [IQR 6338 - 10,173] vs €9150, [IQR 7546 - 12,286] p<0.001). Each euro invested in the platform saved on average €8 of antenatal care resources.

Conclusions

The use of a digital platform for blood pressure and symptom monitoring in antenatal care for high-risk women is associated with lower costs compared to conventional care, while observed maternal and neonatal outcomes are similar.

INTRODUCTION

Up to 10% of pregnancies is complicated by hypertensive disorders, and this proportion continues to rise.[1] Hypertensive disorders of pregnancy (HDP), including gestational hypertension and preeclampsia, are important causes of maternal and perinatal morbidity and mortality, and require intensified surveillance with frequent monitoring.[2] During repeated antenatal visits, maternal as well as fetal condition are checked to detect onset or progression of hypertensive disease. These planned and emergency visits as well as hospital admissions pose a substantial burden to perinatal care resources. [3]

Remote monitoring in addition to antenatal visits has potential to achieve higher-value care for women at high risk for hypertension.[4] Moreover, self-monitoring of blood pressure in pregnancy is increasingly accepted as an alternative to frequent clinic visits.[5,6] Therefore, we developed a digital health platform that allows for repeated blood pressure measurements in combination with preeclampsia symptom reporting during pregnancy.[7] Obstetric care professionals in-clinic monitor these self-measurements and anticipate on values exceeding set thresholds. Together with a predefined antenatal visit schedule from 16 weeks gestational age onwards, this platform was integrated in antenatal care for patients at increased risk of development of preeclampsia.

While patient outcomes and experiences are the primary focus of evaluation of any new intervention, economic impact is also important to allow widespread adoption. Therefore, in this study we performed a cost analysis of use of a digital health platform and new-developed visit schedule in antenatal care for women at risk of hypertensive complications, compared to traditional care without remote monitoring.

We used data of healthcare consumption from the SAFE@HOME study, a case-control study of the digital health strategy, to compare direct healthcare costs as well as societal costs of antenatal care.

METHODS

Study design

In the SAFE@HOME study, a prospective group of pregnant women at risk of preeclampsia used a digital health platform facilitating a novel care pathway. This group was compared with a retrospectively selected group of women managed with traditional monitoring. Methods and results are described in detail elsewhere (Chapter 6).

Population

Pregnant women with a singleton pregnancy were included if they presented for antenatal

care with a new pregnancy in our university hospital (secondary and tertiary level obstetric care) with one of the following risk factors for preeclampsia: chronic hypertension, preeclampsia in a prior pregnancy, or concurrent maternal cardiac or kidney disease.

The prospective group of women (SAFE@HOME group) consisted of women who presented with one of the four risk factors and, after written consent, used the platform in antenatal care. Other inclusion criteria were maternal age >18 years, access to a smartphone/tablet with Internet and knowledge of Dutch or English language. Exclusion criteria were kidney transplant and arm circumference >42 cm, due to technical requirements of the monitor.

For the retrospectively selected control group, a database search was conducted to add women who received perinatal care in our centre for one the four mentioned risk factors at start of pregnancy. Those who delivered between 1-1-2015 and 31-12-2016 were included. Patients younger than 18 years and kidney transplants were excluded. Antenatal care in the control group was traditionally managed based on the Dutch guideline on hypertensive disorders of pregnancy, but without use of home blood pressure monitoring or a fixed antenatal visit scheme.[8]

Intervention

The intervention combined a digital health platform with a predefined (reduced) antenatal visit schedule. The digital health platform includes an app (Luscii, Focuscura, The Netherlands) and the iHealth Track automated blood pressure monitor, validated in a pregnant population.[9] Use of the platform for blood pressure measurements and symptom reporting was found feasible in our hospital setting prior to study start.[7] After informed consent, participants started telemonitoring from 16 weeks of gestation to delivery date, uploading a single blood pressure on Monday-Friday before 10 AM. In case of hypertension (BP >140/>90 mmHg) participants would answer an in-app symptom list with 10 yes/no questions regarding hypertension and pregnancy. Values exceeding set thresholds were visible as alerts for the telemonitoring team of our department, who reviewed the alerts at 10.30 AM. If needed, management was discussed with the consulting obstetrician to further inform or instruct participants at home or ask them to visit the hospital for additional observation or follow-up. All alerts in the dashboard had to be switched off manually after review.

Alongside the use of the platform, a multidisciplinary team of obstetricians, cardiologists nephrologists and patients predefined a uniform antenatal visit schedule, including structure of the scheduled visits and ultrasound assessments (See Chapter 5, Figure 1). This new SAFE@HOME care-pathway, including access to the home-measurements, was embedded in our outpatient department with general visits being performed by hospital-based midwives, gynaecologists in training and supervising obstetricians.

Data collection

Baseline and outcome characteristics

Patient records were used for data collection on baseline characteristics and maternal and fetal/neonatal outcomes of pregnancy and delivery in both groups. Hypertensive disorders of pregnancy were defined according to criteria of the International Society for the Study of Hypertension in Pregnancy (ISSHP).[10] Healthcare consumption of hospital visits, fetal ultrasound assessments, blood/urine analysis, use of medication and all admissions were extracted from the hospital system of participants.

Cost Analysis

This cost analysis used the results of healthcare consumption from one university hospital (2500 deliveries annually, both secondary and tertiary care) that participated in the SAFE@HOME study. Costs were analysed from the perspective of direct healthcare costs, as well as from a societal perspective taking into account work absence and travel costs of study participants and companioning partners. Timeframe of our cost analysis was restricted to antenatal care from the first visit until the admission of delivery, excluding delivery and postpartum care.

For the direct healthcare cost comparison, all procedures regarding antenatal care were obtained from the electronic health records and categorised. The category of outpatient visits included scheduled and unscheduled visits, not followed by hospital admission and performed by hospital midwives or gynaecologist (in training). The ultrasound category included appointments for viability scan and nuchal scan in first trimester, anomaly scan(s) and fetal biometry scans. Number and length of antenatal admissions were also recorded, including reason for admission. The category "Other healthcare costs" included numbers and costs of each individual order for blood and/or urinary analysis, followed by the total costs of all tests performed. Additionally, other diagnostics (such as MRI in pregnancy) were recorded. The last subcategory involved usage of allied health services such as physiotherapists or dieticians. Dutch national tariffs and the Netherlands Healthcare Institute costing manual were used to assign costs to corresponding procedures.[11,12] All costs were converted to 2018 Euros using consumer price indices of Statistics Netherlands. Procedures and costs related to the delivery, postpartum admission and cost of medication use were not included since the scope of this cost analysis was restricted to antenatal care.

Costs associated with the digital health platform were calculated based on time invested by healthcare staff for monitoring purposes, device cost and subscription cost.

For the analysis involving societal costs, data on productivity of study participants and partners were calculated according to Netherlands Healthcare Institute guidelines and were based on figures available from Statistics Netherlands.[13] For travel costs it was assumed that patients lived, on average, 36 km from University Medical Center Utrecht.[14] In the calculations it was assumed that each ultrasound appointment or laboratory test took place on the same day as an outpatient visit or during an admission. For each outpatient visit, the

participants missed 4 hours of work and the partner accompanied the participant with each visit. Maternity leave was not taken into account: since pregnant women have a large degree of freedom when to start leave, no accurate estimation was possible on this matter.

Statistical analysis

Costing data were summarized as medians with interquartile ranges (IQR), for subtotals and totals. For totals, means are also provided. Statistical significance was determined using Mann-Whitney U tests. Categorical outcome variables with counts and percentages were compared between groups using the chi-square or Fisher's exact test. P <0.05 was considered statistically significant. Statistical analysis was performed with IBM SPSS version 25.

Table 1. Baseline characteristics

		SAFE@HOME n = 97	**Control n = 133**	**p-value**
Age (years)	mean (SD)	33.8 (4.5)	33.11 (4.7)	0.229
Body mass index (kg/m2)	mean (SD)	25.3 (4.6)	26.5 (5.8)	0.086
Ethnicity	n (%)			
Caucasian		76 (78.4)	97 (72.9)	0.347
Moroccan / Turkish		14 (14.4)	24 (18.0)	0.466
Afro –Caribbean		4 (4.1)	6 (4.5)	0.887
Other / unknown		3 (3.1)	6 (4.5)	0.584
Education	n (%)			
Primary school or less		3 (3.1)	2 (1.5)	0.652
High school or less		9 (9.3)	5 (3.8)	0.084
Secondary vocational school		35 (36.1)	44 (33.1)	0.636
Higher professional education		26 (26.8)	48 (36.1)	0.137
University graduate		24 (24.7)	34 (25.6)	0.887
Nulliparity	n (%)	30 (30.9)	36 (27.1)	0.523
Smoker	n (%)	2 (2.1)	6 (4.6)	0.472
Psychiatric disorder during pregnancy	n (%)	5 (5.3)	8 (6.3)	0.756
Prior HDP	n (%)	35 (36.1)	68 (51.1)	0.056
Systolic BP at intake (mmHg)	mean (SD)	120 (16.9)	122 (17.8)	0.282
Diastolic BP intake (mmHg)	mean (SD)	74 (12.5)	75 (12.8)	0.417
Risk factor at start of pregnancy	n (%)			
Prior preeclampsia		19 (19.6)	44 (33.1)	0.023
Chronic hypertension		26 (26.8)	45 (33.8)	0.254
Cardiac disease *		35 (36.1)	38 (28.6)	0.227
Kidney disease §		17 (17.5)	6 (4.5)	0.001
Start of telemonitoring	Weeks	17.9 (3.9)	-	-
Duration of telemonitoring	Weeks	20.2 (4.0)	-	-

Legend: BP, blood pressure; HDP hypertensive disorder of pregnancy)

** e.g. maternal congenital heart disease, arrhythmias, valvular heart disease, aortopathy*

§ e.g. (obstetric) antiphospholipid syndrome, systemic lupus erythematosus, chronic kidney disease

RESULTS

In the SAFE@HOME group of the cost analysis, 97 women were prospectively followed during antenatal care with the digital health platform. The control group consisted of 133 women. Demographics including risk factors for hypertensive complications as reason for inclusion are summarized in Table 1. In the telemonitoring group, significantly less women with a history of preeclampsia (19.6 vs 33.1% in usual care, p = 0.023) and more women with kidney disease (17.5 vs 4.5%, p = 0.001) were included. No differences were observed for age, BMI, ethnicity, education level and parity.

Perinatal outcomes

Results of maternal and neonatal outcomes did not significantly differ between the two groups, as shown in Table 2. At time of delivery, incidence of hypertensive diagnoses was similar in both groups, i.e. preeclampsia incidence 19.6% in SAFE@HOME group vs 20.3% in control group (p=0.89). Induction of labour was more common in the SAFE@HOME group. However, no significant differences were found for mode of delivery, gestational age and birth weight at delivery, as well as admission to the NICU.

Healthcare consumption

Use of the predefined visit schedule alongside remote monitoring of blood pressure was associated with less total antenatal visits compared to the control group (median 13 vs 16, p<0.001) (Supplementary Table 1). Ultrasound assessments (median 6 vs 7, p=0.002) and median number of antenatal admission days (median 4 vs 6, p = 0.19) were also lower in the SAFE@HOME group. No difference was found for number of tests of laboratory diagnostics.

Cost analysis

Table 3 shows the costs associated with use of antenatal care services. In the SAFE@HOME group, a significant cost reduction for direct health care costs of 19.7% or €888 (€3616 vs 4504, p = 0.001) was found. This reduction of costs is mainly attributed to the reduction of antenatal visits and antenatal admission days (Supplementary Table 1). Also, a reduction of costs was achieved as more visits were carried out by hospital midwives instead of gynaecologists (in training), as prescribed by the visit schedule. In the analysis 115 euros was taken into account per participant for use of the digital platform and in-clinic monitoring, based on our calculations. For each euro associated with costs of the digital platform, an average of €7.7 was saved for antenatal care resources.

In the additional analysis, costs from a societal perspective were added to direct health care costs. Both travel costs (€245 vs. €280, p<0.001) and loss of productivity costs (€3565 vs €4329, p<0.001) were lower for the SAFE@HOME group.

Combined cost calculations of antenatal care resulted in total savings in healthcare costs and societal costs of 18.2% or €1665 (€7485 vs €9150, p < 0.001).

Table 2. Pregnancy outcomes

		SAFE@HOME n = 97	Control n = 133	p-value
Final maternal diagnosis of HDP in current pregnancy	n (%)			
Gestational hypertension		7 (7.2)	4 (3.0)	0.210
Preeclampsia		19 (19.6)	27 (20.3)	0.894
HELLP		1 (1.0)	0 (0.00	0.422
Chronic hypertension without PE		22 (22.7)	26 (19.5)	0.564
NO HDP (normotensive)		48 (49.5)	76 (57.1)	0.250
Suspected fetal growth restriction	n (%)	12 (12.4)	13 (9.8)	0.532
Steroids administration	n (%)	15 (15.5)	10 (7.5)	0.056
MgSO4 administration	n (%)	9 (9.3)	12 (9.0)	0.947
Use of anti-hypertensive drugs <20 w GA	n (%)	37 (38.1)	41 (30.8)	0.247
Use of anti-hypertensive drugs >20 w GA	n (%)	53 (54.6)	58 (43.6)	0.098
iv antihypertensive drugs ante partum	n (%)	4 (4.1)	9 (6.8)	0.391
Iv antihypertensive drugs post partum	n (%)	6 (6.2)	4 (3.0)	0.392
Mode of delivery				
Induction of labour	n (%)	54 (55.7)	51 (38.3)	0.009
*because of hypertension	n (%)	29 (53.7)	28 (54.9)	0.902
Primary caesarean section	n (%)	23 (23.7)	34 (25.6)	0.748
*because of hypertension	n (%)	6 (26.1)	12 (35.3)	0.463
Vaginal delivery	n (%)	56 (57.7)	72 (54.1)	0.588
Instrumental delivery	n (%)	9 (9.3)	6 (4.5%)	0.148
Secondary caesarean section	n (%)	9 (9.3)	21 (15.8)	0.148
Fetal/neonatal outcome				
GA at delivery (w)	mean (SD)	38.3 (2.1)	38.8 (2.3)	0.167
Preterm birth <37+0	mean (SD)	13 (13.4)	20 (15.0)	0.727
Birth weight (g)	n (%)	3069 (650)	3203 (694)	0.137
Birth weight <5th percentile	n (%)	5 (5.2)	12 (9.0)	0.268
APGAR <7 at 5 minutes	n (%)	3 (3.1)	7 (5.3)	0.525
NICU admission	n (%)	2 (2.1)	6 (4.5)	0.473
Antepartum fetal death*	n (%)	1 (0)	0 (0)	0.422

Legend: GA, gestational age; HDP hypertensive disorder of pregnancy; PE, preeclampsia

*Table 3. Costs of antenatal care. All data are euros expressed as medians [interquartile ranges] except for rows indicating means of Total costs for healthcare and Total costs, marked with an *.*

	SAFE@HOME n=97		**Control n=133**		**Diff.**	**p-value**
Antenatal visits	1862	[1522 - 2198]	2202	[1826 - 2627]	340	0,000
Obstetrician (or in training)	1530	[1190 - 1870]	2040	[1275 - 2380]	510	0,000
Midwife	324	[203 - 486]	243	[81 - 689]	-81	0,026
Ultrasound visits	508	[423 - 592]	592	[508 - 761]	85	0,002
Antenatal admissions						
All patients - total	0	[0 - 1336]	0	[0 - 2672]	0	0,202
Admitted patients only:						
All indications	2672	[1336 - 6680]	4008	[1336 - 12,692]	1336	0,415
For PE/HT until delivery	0	[0 - 6012]	0	[0 - 1336]	0	0,238
For PE/HT for observation only	0	[0 - 0]	0	[0 - 1336]	0	0,007
Other Healthcare Costs						
Laboratory	306	[199 - 411]	297	[203 - 420]	-9	0,692
Other diagnostics	0	[0 - 93]	0	[0 - 46]	0	0,255
Other healthcare costs	0	[0 - 0]	75	[0 - 121]	75	0,000
Telemonitoring	115	[115 - 115]	0	[0 - 0]	-115	0,000
Total healthcare costs, median	3616	[3071 - 5329]	4504	[3515 - 6923]	888	0,001
*** Total healthcare costs, mean**	5805		7143		1338	
Travel costs	245	[192 - 280]	280	[245 - 325]	35	0,000
Productivity loss	3565	[2915 - 4374]	4329	[3565 - 5093]	764	0,000
TOTAL COSTS -median	7485	[6338 - 10,173]	9150	[7546 - 12,286]	1665	0,000
*** Total costs- mean**	9874		12048		2174	

Legend: Diff, difference; PE, preeclampsia; HT, hypertension

DISCUSSION

Main findings

In the SAFE@HOME study, antenatal care with use of a digital health platform and predefined visit schedule was compared to traditional monitoring of women at increased risk of hypertensive complications in pregnancy. In the SAFE@HOME group, a reduction was found in antenatal visits, ultrasound assessments and antenatal hypertension-related admission, compared to the control group. This study found no differences with regards to (adverse) perinatal outcomes between the two groups.

Results of the cost analysis showed a significant cost reduction for costs of antenatal care services; €3616 in the SAFE@HOME group compared to €4504 in conventional care, median cost difference €888, p = 0.001. This result accounted for a 19.7% cost reduction. When comparing means of total healthcare costs, a difference was found of € 1338 or 18.7% (€5805 vs €7143). Reduction of costs was primarily related to a reduction in clinic visits and a shift of type of obstetric care professionals that performed these visits. Moreover, a shorter length of antenatal hospital admissions was found in the SAFE@HOME group. When adding costs of travelling and work absence (societal costs), costs decreased from €9150 in usual care to €7485 with use of the digital platform (median cost difference €1665 or 18.2%, p<0.001) (mean cost difference €2174).

Comparison with the literature

Several cost studies of home- or self-monitoring of blood pressure in the hypertensive pregnant population have been performed recently.[15-17] In our study, telemonitoring was started before 20 weeks of gestation. In contrast, participants in the published studies started remote monitoring later in pregnancy, when hypertensive complications occurred, meaning at time of diagnosis of hypertension. In these studies, self-monitoring of blood pressure also resulted in cost savings, mostly achieved by a reduction in hospital visits and antenatal admissions as compared to conventional surveillance. For example, Xydopoulos et al. found a saving of EUR 226-323 per patient per week of home monitoring after diagnosis of hypertension with their results of a case-control study.[17] In the cost-modeling study of Barton et al, outpatient management of patients with gestational hypertension was found cost-effective as the need for inpatient care decreased.[15] Only one study used in-clinic monitoring of patients' home measurements. [16]

The use of our digital platform was associated with a reduction of health care consumption and thus with a total reduction of costs. These reductions are consistent with recent studies of remote pregnancy monitoring in different settings (i.e. start of home-monitoring at diagnosis of hypertension in pregnancy).[18-19] Therefore, blood pressure and symptom monitoring with help of a digital platform is likely to be a cost-saving approach to antenatal care.

Strengths and limitations

Strength of this study is the direct data extraction of healthcare consumption from electronic patient files of our study center. These data allowed a factual, real life comparison of direct healthcare costs between groups. For the costs associated with use of the digital health platform, a precise calculation was made based on acquisition of blood pressure monitors, subscription fees of the dashboard and time spent by obstetric care professionals in the telemonitoring team for daily monitoring of abnormal values. Addition of these costs to the direct healthcare costs of the telemonitoring participants allowed a complete interpretation of differences between groups. We compared groups of women with risk factors for (development of) preeclampsia at intake, and therefore we were able to compute costs of full antenatal care up to delivery. The results of the cost analysis therefore reflect clinical practice of antenatal follow-up in this risk group, which aids the applicability and generalizability for similar health care settings. Finally, a major strength of this study is the addition of societal costs of travelling and productivity loss due to complete follow-up to the analysis. These results extend the overview of costs associated with care for pregnant women at risk of hypertensive complications.

There are several limitations to the study. The retrospective nature of the control group might have caused substantial selection bias. The two groups were similar regarding to all baseline characteristics, however more women with pre-existent kidney disease, and less women with a history of preeclampsia were included in the SAFE@HOME group. Furthermore, women with arm circumference over 42 were excluded for participation in this group. These differences may have influenced the results of pregnancy outcomes and therefore healthcare consumption and costs. In general, cost analyses are made with calculations based on assumptions of costs for Dutch healthcare, which could hamper extrapolation of results to other countries or settings. Our analysis was restricted to antenatal care costs. As there were no significant differences in perinatal outcomes between groups, especially with regards to mode of delivery and neonatal outcome, it is legitimate to provide an overview of costs of antenatal care only. [17]

Interpretation and further research

The use of mobile-health technology to assist antenatal care has been suggested before for its advantages regarding access to care, enhanced satisfaction and reduction of health care consumption.[4,20,21] However, to implement eHealth-enhanced strategies in antenatal care, a deliberate approach is needed before widespread implementation. Alongside evaluation of effects of telemonitoring on perinatal outcome and patient satisfaction, economic evaluations are needed to determine the added value of digital health strategies.

Cost analysis as performed in this study is of interest to both health care providers, pregnant women and other stakeholders in the process of decision-making in the future of healthcare. For decisions on funding and adoption, governments on national, European and global levels

will need health technology assessments.[22] Using the much-needed results of the economic effects of digital health interventions, the advantages to healthcare can be put in perspective to enable further research and implementation.[23] Moreover, an increase of availability of data on outcome and cost effects must help overcome present issues regarding reimbursement and coverage of digital care services.

Conclusion

Use of the new visit schedule using the digital health platform of SAFE@HOME is associated with lower costs of antenatal care for women at increased risk of preeclampsia. Furthermore, total costs, including societal costs, were also significantly reduced, compared to traditional follow-up in high-risk pregnancy. In our sample, similar maternal and neonatal outcomes were found. Each euro associated with costs of the digital platform, saved almost €8 on average on antenatal care resources. Digital health interventions for monitoring of (risk of) hypertension in pregnancy are promising tools to achieve higher-value antenatal care.

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	# of procedures (median)				Cost in Euro (median)			
	Safe@Home (n=97)	Regular Care (n=133)	Diff (#)	p-value (#)	Safe@Home (n=97)	Regular Care (n=133)	Diff (€)	p-value
Out-Patient Visits								
All Out-Patient Visits								
Total	13 [11 - 16]	15 [14 - 18]	2	**0,000**	1862 [1522 - 2198]	2202 [1826 - 2627]	340	0,000
GA 0-26	6 [4 - 7]	6 [5 - 7]	0	0,454	761 [543 - 1012]	850 [579 - 1101]	89	0,099
GA 26-34	3 [3 - 5]	4 [3 - 5]	1	**0,019**	510 [340 - 676]	591 [421 - 850]	81	**0,043**
GA 34-delivery	4 [2 - 5]	5 [4 - 7]	1	**0,000**	502 [336 - 672]	761 [510 - 923]	259	**0,000**
Physician (in training)								
Total	9 [7 - 11]	12 [7.5 - 14]	3	**0,000**	1530 [1190 - 1870]	2040 [1275 - 2380]	510	**0,000**
GA 0-26	3 [2 - 5]	5 [2 - 6]	2	**0,013**	510 [340 - 850]	850 [340 - 1020]	340	**0,018**
GA 26-34	3 [2 - 3]	3 [2 - 5]	0	**0,030**	510 [340 - 510]	510 [340 - 850]	0	**0,038**
GA 34-delivery	2 [1 - 3]	4 [2 - 5]	2	**0,000**	340 [170 - 510]	680 [340 - 850]	340	**0,000**
Midwife								
Total	4 [2.5 - 6]	3 [1 - 8.5]	-1	**0,026**	324 [203 - 486]	243 [81 - 689]	-81	**0,026**
GA 0-26	2 [1 - 3]	1 [0 - 3]	-1	**0,013**	162 [81 - 243]	81 [0 - 243]	-81	**0,010**
GA 26-34	1 [0 - 2]	0 [0 - 2]	-1	0,280	81 [0 - 162]	0 [0 - 162]	-81	0,256
GA 34-delivery	1 [0 - 2]	1 [0 - 4]	0	0,788	81 [0 - 162]	81 [0 - 324]	0	0,738
Ultrasounds								
Total	6 [2 - 10]	7 [6 - 9]	1	0,002	508 [423 - 592]	592 [508 - 761]	85	**0,002**
GA 0-26	3 [2 - 4]	3 [2 - 5]	0	**0,000**	254 [169 - 338]	254 [169 - 423]	0	**0,000**
GA 26-34	2 [2 - 3]	2 [2 - 3]	0	0,552	169 [169 - 254]	169 [169 - 254]	0	0,651
GA 34-delivery	1 [0 - 1]	1 [0 - 1]	0	***0,050***	85 [0 - 85]	85 [0 - 85]	0	**0,048**
Antenatal Admission Days								
All Patients								
Total	0 [0 - 2]	0 [0 - 4]	0	0,187	0 [0 - 1336]	0 [0 - 2672]	0	0,202
Admitted Patients only								
Total	4 [2 - 10]	6 [2 - 19]	2	0,415	2672 [1336 - 6680]	4008 [1336 - 12,692]	1336	0,415
For PE/HT until delivery	0 [0 - 9]	0 [0 - 2]	0	0,238	0 [0 - 6012]	0 [0 - 1336]	0	0,238
For PE/HT for observation	0 [0 - 0]	0 [0 - 2]	0	**0,007**	0 [0 - 0]	0 [0 - 1336]	0	**0,007**
Other Healthcare								
Lab	62 [43.5 - 93.5]	59 [37 - 91.5]	-3	0,439	306 [199 - 411]	297 [203 - 420]	-9	0,692
Orders	9 [6 - 14]	9 [6 - 14]	0	0,880	101 [68 - 158]	101 [68 - 158]	0	0,880
Determinations[i]	52 [38 - 82]	49 [30 - 77]	-3	0,350	183 [124 - 259]	189 [129 - 272]	6	0,663
Diagnostics (excl. Lab)	0 [0 - 2]	1 [0 - 3]	1	**0,003**	0 [0 - 93]	0 [0 - 46]	0	0,255
Other Healthcare *	0 [0 - 0]	2 [0 - 4]	2	**0,000**	0 [0 - 0]	75 [0 - 121]	75	**0,000**
Telemonitoring	1 [1 - 1]	0 [0 - 0]	-1	**0,000**	115 [115 - 115]	0 [0 - 0]	-115	**0,000**
Total Healthcare Costs					3616 [3071 - 5329]	4504 [3515 - 6923]	888	**0,001**

[i]) Determinations are individual substances determined via blood analysis such as glucose, ALAT, Urea, etc.

*) Includes Allied Health Services such as dieticians and physiotherapy.

p-values for medians derived with Mann-Whitney-U Test, bold numbers represent values <0.005

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6

CHAPTER 7

USER EXPERIENCES WITH AND RECOMMENDATIONS FOR MOBILE HEALTH TECHNOLOGY FOR HYPERTENSIVE DISORDERS OF PREGNANCY: MIXED METHODS STUDY

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ABSTRACT

Background

Hypertensive disorders of pregnancy (HDP) are a primary cause of adverse maternal and neonatal outcomes worldwide. For women at risk of hypertensive complications, guidelines recommend frequent surveillance of blood pressure and signs of preeclampsia. Clinic visits range from every 2 weeks to several times a week. Given the wide ubiquity of smartphones and computers in most countries and a growing attention for self-management, digital technologies, including mobile health (mHealth), constitute a promising component of monitoring (self-measured) blood pressure during pregnancy. Currently, little is known about the experiences of women using such platforms and how mHealth can be aligned with their needs and preferences.

Objective

The objectives were twofold: (1) to explore the experiences of Dutch women who had an increased risk of HDP with a blended care approach (mHealth combined with face-to-face care) for remote self-monitoring of blood pressure and preeclampsia symptoms and (2) to formulate recommendations for the use and integration of mHealth in clinical care.

Methods: Alongside a prospective blended care study (SAFE@home study) that monitors pregnant women at increased risk of HPD with mHealth technology, a mixed methods study was conducted, including questionnaires (n=52) and interviews (n=11). Results were analyzed thematically.

Results

Of the 4 themes, 2 themes were related to the technologies themselves (expectations, usability), and 2 themes were related to the interaction and use of mHealth (autonomy and responsibilities of patients, responsibilities of health care professionals). First, the digital platform met the expectations of patients, which contributed to user satisfaction. Second, the platform was considered user-friendly, and patients favored different moments and frequencies for measuring their blood pressure. Third, patient autonomy was mentioned in terms of increased insight about their own condition and being able to influence clinical decision making. Fourth, clinical expertise of health care professionals was considered essential to interpret the data, which translates to subsequent responsibilities for clinical management. Data from the questionnaires and interviews corresponded.

Conclusions

Blended care using an mHealth tool to monitor blood pressure in pregnancy was positively evaluated by its users. Insights from participants led to 7 recommendations for designing and implementing similar interventions and to enhance future, morally sound use of digital technologies in clinical care.

INTRODUCTION

Mobile health (mHealth) refers to the use of mobile devices, mobile phones, and wireless technologies to support the achievement of health objectives.[1] mHealth is expected to improve access to care, enhance patient satisfaction, and reduce clinic visits and admissions without compromising safety of care and is argued to improve interaction with and participation of better-informed and more active patients.[2-4] To date, mHealth has mostly focused on patients with chronic conditions or healthy individuals to improve healthy lifestyle habits.[5-7] As in other domains of health care, including pregnancy care, a shift is currently occurring from hospital-based to home-based services.[8] In search of improved care for pregnant women, tailored care with the integration of mHealth has been suggested as an addition to or partial replacement of frequent prenatal visits.[9] This approach is called blended care, where digital technologies are combined and integrated with face-to-face care. While many of these technologies are being developed and implemented, little is still known about clinical outcomes including safety, effectiveness, patient satisfaction, and ethical considerations.

Hypertensive disorders of pregnancy (HDP) are a primary cause of adverse maternal and neonatal outcomes worldwide and occur in 10% of pregnancies.[10] Risk groups for hypertensive complications include women with chronic hypertension, diabetes, obesity, renal disease, cardiac disease, and preeclampsia in a prior pregnancy. The proportion of women with these risk factors has been steadily rising over recent years.[10] For women considered to be at risk, guidelines recommend frequent observation of the fetal condition and the pregnant woman's blood pressure and signs of preeclampsia.[11] Planned and unplanned visits can range from every 2 weeks to 4 times a week or even daily. The burden of these recurrent visits is significant, for both patients and their spouses and family, as well as for health care services. However, the incidence of preeclampsia with severe features is approximately 3%[12], meaning that a substantial number of monitored women, while at risk, do not develop this condition.

Given the wide ubiquity of smartphones and tablets in most countries, mHealth is a promising alternative for monitoring hypertension during pregnancy. The latest research has shown that pregnant women are willing to undertake repeated self-measurements and a majority of women would like to be involved in their blood pressure management[14,13] and regard remote monitoring important for their pregnancy follow-up.[15] Little is known about the experiences of women using such platforms and how these digital tools can be aligned with their needs and preferences.

This study aimed, firstly, to explore how pregnant women, who have used mHealth as part of a blended care approach for repeated blood pressure measurements and preeclampsia

symptom reporting, experience the use of such technology. Second, the study aimed to formulate recommendations based on these user experiences. Based on the insights originating from the users' experiences, we identified several recommendations to design and implement similar interventions and to enhance future use of digital technology in clinical care.

METHODS

A mixed-methods study, alongside a prospective blended care study (SAFE@home study).[16,17] was performed to explore the understanding of patients' experiences with mHealth.[18,19] Data were collected by means of validated questionnaires and semistructured in-depth interviews with patients that had experience with mHealth for remote monitoring of HDP, to explore their experiences and motivations. The research ethics committee of the University Medical Center Utrecht determined that this study was exempt from the Medical Research Involving Humans Act (reference number 18-898-C).

Context of the Blended Care Approach in Prenatal Care

The overarching prospective study, named Safe@Home, evaluates the use of mHealth technology to remotely monitor blood pressure and preeclampsia symptoms. The data collected within this study were sent by the patient to the digital monitoring team, who reviewed the data each day except for the weekend days. The mHealth technology consisted of an automated blood pressure monitor with Bluetooth connection to a smartphone app for iOS users and a web-based portal for Android users.[16,17] Digital monitoring started from 16 weeks gestational age and was continued until delivery, with interruption in case of hospital admission. Participation in the blended care approach was offered to pregnant women whom, at intake, presented with one of the following risk factors for hypertensive complications: chronic hypertension, history of prior preeclampsia, or maternal cardiac or renal disease requiring prenatal care in our clinic in the University Medical Centre Utrecht (university hospital) or Diakonessenhuis Utrecht (general teaching hospital). Access to a smartphone or tablet with internet connection and good understanding of either the Dutch or English language were required. More information about the overarching study can be found in previous publications.[16,17]

A prenatal visit schedule was predefined for this group of patients, with a reduced number of visits while continuing remote monitoring. Participants were asked to measure their blood pressure every weekday before 10 AM and at least 1 hour after waking up. A 9-question symptom score list could be answered in case of hypertension. Predetermined thresholds (systolic blood pressure >140 mm Hg, diastolic blood pressure >90 mm Hg) or self-reported symptoms of preeclampsia in the questionnaire resulted in automatically generated alarm signals on a monitoring dashboard in the hospital. For health care providers, a web portal provided online access to patient-reported questionnaires and blood pressure data. Members

of the digital monitoring team (midwives or obstetric nurses) reviewed the data every morning from the outpatient department. The combination of blood pressure measurement and the presence of symptoms was reviewed and if needed, the digital monitoring team could consult the obstetrician for advice. Subsequently, participants were contacted to advise about management or follow-up. The platform was embedded into prenatal care with the use of a reduced predefined prenatal visit schedule, with regular appointments in the outpatient department carried out by hospital midwives and gynecologists (in training).

Data Collection

Questionnaires

At 36 weeks of gestation, two questionnaires were sent by email to all participants of the prospective study. One questionnaire assessed the usability of the mHealth technology (via an app or web portal) and the connected devices, focusing on the ease of use and given instructions. This usability questionnaire consisted of 9 propositions rated on a 5-point Likert scale (strongly agree to strongly disagree) to obtain quantifiable scores (see Textbox 1). Furthermore, the use of the blood pressure monitor, usability of the smartphone app, and content of the app could be rated on a scale from 1 to 10. The usability questionnaire was generated by the study team and not validated before the start of the study. The second questionnaire was the validated Client-Centered Care Questionnaire (CCCQ). The CCCQ was developed as an instrument to measure client-centeredness as experienced by clients of care organizations and to evaluate the effects of interventions aimed at improving the client-centeredness of care services.[20] Themes of the CCCQ include recognition, respect, autonomy, and partnership as perceived by the participants. It consists of 15 questions rated on a 5-point Likert scale, ranging from "totally disagree" to "totally agree" (Multimedia Appendix 1). Results of the CCCQ can be interpreted using a unidimensional application. This is done by aggregating all information in one measure and calculating a total test score. This total score expresses care receivers' perception of client-centered care, with higher scores representing higher perceived client-centered care. Separate questions are discussed thematically, in line with the qualitative results of this study.

Textbox 1. Items on the usability questionnaire.

- The system and its use were easy to understand.
- I felt at ease using the system during pregnancy.
- While using the system, I was able to continue my daily activities.
- I am satisfied with the ease of use of this system.
- I would recommend this system to other pregnant women.
- The instructions for use of the blood pressure monitor were clear.
- The instructions for use of the app were clear.
- It was clear when to provide my measurements.
- It was clear when to contact my health care provider.

Interviews

Semistructured in-depth interviews were conducted with participants of the overarching study after an email invitation. Patients who were willing to be interviewed and were able to speak either Dutch or English were included in the interview study through purposive sampling. The topic list was designed to include the motivations, experiences, and perspectives of patients using the platform. The semistructured format provided participants with the opportunity to discuss matters they believed needed emphasis, while offering guidance throughout the interview. Questions for the interview guide were based on preliminary quantitative results from our questionnaires, which suggested the importance of technical functioning, communication with care providers, and implications for autonomy. The topic list was expanded based on the literature on ethical aspects of digital health, mHealth, and digital monitoring. Interviews were conducted by KJ (assistant professor) and MD (research assistant), both female researchers with experience in qualitative studies using interviews. No relationship with participants was established prior to the interviews. The interviews were conducted until saturation was reached, meaning that no new perspectives or themes were found in consecutive interviews and no new themes emerged from the data. Verbatim transcriptions of interviews and interviewers' notes were compared with audio recordings to check for accuracy. Transcripts were imported into NVivo12 and analyzed thematically, combining inductive and deductive analyses. KJ and MD started with an a priori coding scheme to allow for deductive coding based on topics described in the literature (responsibilities, shared decision making, patient empowerment, motivations). Codes and their meanings were discussed among the research team prior to coding to guarantee intercoder reliability. The inductive part of the thematic analysis combined methods of close reading and constant comparison; codes emerging from the transcripts were clinical expertise, reassurance, burden and stress, and understanding one's own condition. Codes were examined and systematically reviewed for supporting or conflicting evidence concerning emerging themes and codes. We also explored whether there were any differences between nulliparous and parous women and between women with a history of HDP and those without. Where relevant, we explicitly address these differences in the results. Results are reported using the Consolidated Criteria for Reporting Qualitative research checklist.

RESULTS

Patient Characteristics

Of 103 invited participants, a total of 51 participants completed both questionnaires, and one participant only completed the CCCQ (total n=52). The interviews were conducted with 11 women (8 after delivery, 3 during pregnancy) and comprised the qualitative part of this study. All interviews (n=11) took place by phone, as preferred by the participants, and lasted between 35 minutes and 58 minutes. The majority of the interviewed women (8/11) also completed the questionnaires.

The demographic data of both groups are shown in Table 1. Obstetric characteristics of relevance to this topic are indicated for the interviewees and questionnaire participants (see Table 1).

After analysis of the data from the interviews and questionnaires, we identified 4 themes. Of these, 2 themes were related to the mHealth technology itself (themes 1 and 2), and 2 themes were related to the interaction with and use of the technology (themes 3 and 4).

Table 1. Patient characteristics.

	Questionnaires n=52	**Interviews n=11**
Maternal age (years), mean (SD)	34.4 (4.1)	34.2 (2.5)
BMI (kg/m2), mean (SD)	24.9 (4.6)	23.9 (2.5)
Ethnicity, n (%)		
Caucasian	47 (90.4)	11 (100)
Afro-Caribbean	0 (0)	0 (0)
Mediterranean	3 (5.8)	0 (0)
Other	2 (3.8)	0 (0)
Level of education, n (%)		
Primary school	1 (1.9)	0 (0)
Secondary school	4 (7.7)	0 (0)
Middle-level applied education	14 (26.9)	3 (27.3)
Higher-level applied education	17 (32.7)	6 (54.5)
Scientific education (university)	13 (25.0)	2 (18.2)
Unknown	3 (5.8)	0 (0)
Nulliparous, n (%)	19 (36.5)	2 (18.2)
HDP prior pregnancy, n (%)		
None	14 (26.9)	3 (27.3)
Chronic hypertension	1 (1.9)	1 (9.1)
Gestational hypertension	5 (9.6)	2 (18.2)
Preeclampsia/HELLP	13 (25.0)	3 (27.3)
Not applicable (nulliparous)	19 (36.5)	2 (18.2)
Initial diagnosis at start of SAFE@home study		
Preeclampsia in prior pregnancy	10 (19.2)	2 (18.2)
Chronic hypertension	17 (32.7)	5 (45.5)
Cardiac disease	17 (32.7)	3 (27.3)
Renal disease	8 (15.4)	1 (9.1)
HDP current pregnancy, n (%)		
None	23 (44.2)	2 (18.2)
Chronic hypertension	14 (26.9)	3 (27.3)
Gestational hypertension	6 (11.5)	2 (18.2)
Preeclampsia	9 (17.3)	4 (36.4)

Legend: HDP: hypertensive disorders of pregnancy, HELLP: hemolysis, elevated liver enzymes, low platelet count.

Theme 1: Expectations of and Satisfaction With the mHealth Technology

Quantitative Analysis

Analysis of the usability questionnaire showed that almost all participants (49/51, 96%) felt comfortable using mHealth. The vast majority (45/51, 88%) would recommend it to their friends and family, especially participants who had been pregnant before (97% of multiparous vs. 74% of nulliparous women). Overall, client-centeredness of the blended care approach, based on the CCCQ, was rated at an average 57.5 of 75 points (range 36-75 points), which translates to a score of 77 from a possible total score of 100. This total CCCQ score was comparable between nulliparous women (score of 76, n=19) and parous women (score of 77, n=33). Of all parous women, women with prior HDP (19/33) scored the CCCQ slightly higher (score of 79/100) than those without experience with HDP (14/51; 75/100).

Qualitative Analysis

In order to understand what is important for mHealth users, we asked the interview participants what their expectations were before they started using the digital technology in the Safe@Home study and whether their expectations were met. The most often mentioned motivations to start using the technology were the expected reassurance of being closely monitored by a health care professional (9/11; 2 nulliparous and 7 parous), better pregnancy outcomes (6/11; 3 with a history of hypertension and 3 with a history of HPD), and the prospect of fewer hospital visits (5/11; none with a history of HPD). This aligned well with their experiences; most interview participants (8/11) reported they felt reassured and safe because of the close monitoring by their obstetric care professional. The use of mHealth reduced the frequency of visits, which contributed to the users' wellbeing and a more relaxed pregnancy experience (9/11; 2 nulliparous and 7 parous). The blended care approach also enabled timely preventative measures or interventions, which resulted in early detection of abnormalities or risks (2/11). All interview participants considered it a benefit to be able to measure their own blood pressure, especially when they experienced symptoms associated with preeclampsia.

Table 2. Quotes illustrating interviewees' expectations and satisfaction.

Topic	Quotes
Reassurance	More relaxed, I'd say. I haven't worried at all about my blood pressure. I considered it under control [...] Because you do it continuously [the measurements], it reassures you. (P1)
	It is very pleasant and extremely easy. It's reassuring that you are being monitored [by health care professionals]. (P11)
Frequency of visits	It has given me peace of mind over all those months, primarily because of the significantly reduced number of clinical visits. (P1)
	It is ironic; we expected it because it was announced like that, that we would have to visit the hospital less often, because we would be monitored via the app, but it resulted in more frequent contact. (P5)

Also, when their measurement indicated normal blood pressure, the digital monitoring was considered useful and reassuring, because it would indicate that the symptoms were not caused by hypertension. Comparable to the results of the questionnaire, all interviewed women would recommend the system to other pregnant women.

Some reflections of the interview participants indicated that their expectations did not always match their experiences. A few women were surprised by health care professionals calling when they did not expect it, while at other times, they were not called by the health care professional when they expected it based on their uploaded blood pressure data (2/11; both with a history of hypertension). Participants who needed reassurance that their blood pressure or symptoms were nothing to worry about sometimes called the hospital themselves. Furthermore, one interview participant needed several extra hospital visits because of hard-to-control hypertension, eventually leading to hospital admission. As a result, she was somewhat disappointed that the digital monitoring platform did not live up to her expectations (P5, Table 2).

Theme 2: Usability of the mHealth Tool

Quantitative Analysis

Analysis of the questionnaires showed that nearly all participants considered the user instructions of the blood pressure monitor (49/51, 96%) and smartphone app or website (48/51, 94%) to be clear and understandable. Similarly, almost everyone (49/51, 96%) found it easy to learn how to use the mHealth technology.

Furthermore, the vast majority of participants (47/51, 92%) was satisfied with the usability of the mHealth technology; 81% (41/51) of the participants said the daily measurements took ≤5 minutes a day (average 4.57 minutes, range 3-15 minutes), and women could easily continue their daily routine while using the technology (50/51, 98%). Some found it difficult to combine digital monitoring with their daily routine (5/51, 10%).

On a scale from 1 to 10, the blood pressure monitor was rated at 8.5 (range 6-10), usage of the smartphone app at 7.6 (range 1-10), and content of the smartphone app at 7.8 (range 1-10).

Qualitative Analysis

Similar to the questionnaire, interview participants (6/11) considered the app to be "modern" and easy to use; all users of the web portal (4/11) suggested that an Android app would be more user-friendly. Moreover, the iOS app was regarded to be comprehensive; the symptom survey was considered short but clear and easy to complete — it did not take them much effort and time (4/11; 2 with a history of HPD and 2 without). Other technical aspects that contributed to the ease of use were the reminder function, automatic Bluetooth synchronization, and perceived high accuracy of the measurement. A couple of participants (2/11) noted that technical understanding of the functioning of the app was irrelevant for their user experience.

A few users mentioned that measuring early in the morning was not always easy to combine with either commuting to work or "family rush hour" in the morning (3/11) or not representative, as their morning blood pressure was naturally low (1/11). These users preferred to have the option to measure in the evening instead of the morning. Most considered measuring 5 times a week sufficient; a couple of interview participants measured every day, even during weekends, either because of worries about her medical condition (1/11; with a history of HPD) or to allow it to become a habit in their daily routine (2/11). Multiple mHealth users (4/11) measured several times a day when they experienced symptoms of preeclampsia or hypertension. At the same time, others (6/11; 4 with a history of HDP) mentioned that daily measurements were too burdensome or medicalizing, especially when they perceived their symptoms or blood pressure to be stable. A couple of interviewees (2/11) mentioned they missed the mHealth tool after giving birth and would have wanted to continue to measure during their postpartum period.

A couple of women (2/11) mentioned technical errors in the synchronization of their measurements with the system used in the hospital. Furthermore, a couple of others (2/11; both parous and with a history of hypertension) felt that the symptom score list to monitor preeclampsia signs was at times confusing because some questions did not match the specific pregnancy term. In particular, the question "Can you feel the baby move?" was considered to be upsetting in the first trimester. Also, one interview participants considered the orange or red lights stressful, as she never saw a green light because of her high values (P9, with a history of HPD; Table 3).

Table 3. Quotes illustrating interviewee perspectives on the usability of the mHealth tool.

Topic	**Quotes**
App vs web portal	At first, I used the web portal, but when I had a closer look, I realized that the app is much easier, because it automatically synchronizes. It is so easy! (P1)
Frequency of measurement	Before I started, I thought it would be burdensome to measure my blood pressure every day and was not convinced that it would be necessary. [...] But eventually, it was very easy. It became part of my routine to measure in the morning before going to work or before bringing the children to school. (P8)
	The app was meant to be used in the morning, which was somewhat a downside, because my blood pressure is fine in the morning. (P3)
	While I was using it, no [I did not experience anything unexpected], but after giving birth and being back home, I continued measuring with my own device, because I missed that sort of information about my body. (P7)
Questions suitable to term	Those questions did not really match with being in the first trimester. Because it asked for example "do you feel contractions," "do you still feel the baby move," But [at that time], I hardly had a belly, and I couldn't even feel the baby yet. [..] I found it difficult and puzzling. (P10)
Alarms	"Those lights [on the blood pressure device], they should get rid of in favor of people who are easily stressed out. It showed orange so often. Since my blood pressure has been high my whole life, you feel like there is a continuous alarm, while yeah, that was not really the case." (P9)

Table 4. Quotes illustrating interviewee perspectives on autonomy and responsibilities of patients.

Topic	Quotes
Being informed	I experienced that I thought I was going to measure hypertension because I felt a headache, but then I didn't measure anything abnormal. That is odd. But exactly because of such experiences, I consider it beneficial to be able to measure, because it provided objective information to really judge it. Because I find it difficult to determine what is the matter, simply by how I feel. (P8)
	I then understood, you know, why they [health care professionals] ask you all these questions and that these are relevant. Because of the symptom score list or due to hypertension and related symptoms of preeclampsia, that I became aware that once you experience such symptoms, you shouldn't think it's normal, but that you have to inform health care professionals. (P2)
Information for lifestyle	It is information, you know. I had to take care of my activity level; when I did not measure hypertension, I would go outside for example. […]. And in case I would measure hypertension, I would take it easy and ask my husband to take care of the children. It provides information relevant for such activities. That was very helpful. (P8)
Responsibilities	[..] but it is also your own responsibility, the responsibility of the mother or the pregnant woman. Not only because you know your body best, but also because you become aware of aspects because of this research study. And then it's my responsibility to discuss it with the health care professional. (P2)
Control	You both have access to the information. What I see in my overview, the physician can also see, so you can also look at it together. I got the impression that more deliberation is possible, that you do it together like how should I interpret this and the physician can explain it for example. (P8)

Theme 3: Autonomy and Responsibility of Patients

Quantitative Analysis

Respondents of the questionnaires were positive about their role within the blended care approach. The majority of the participants felt they were given sufficient opportunity to draw on their own knowledge and experience (40/51, 77%) and to decide about the kind of care they receive (43/52, 83%). Furthermore, they felt they were given enough opportunity to do what they were capable of doing themselves (47/52, 90%). However, only half of the participants (26/52, 50%) felt like they were given enough opportunity to arrange and organize prenatal care themselves. Some (30/52, 57%) would like even more influence in clinical decision making and felt that health care professionals are sometimes too quick to deny a possibility. A minority of the participants (21/52, 40%) felt like they had a say in deciding when the care was provided.

Qualitative Analysis

Interview participants noted two dimensions related to patient autonomy. First, all interview participants (11/11) mentioned that mHealth helped to be informed about HDP. Insights on blood pressure over time, as displayed in a trend line in their app, was especially considered to be informative (6/11; all parous). Such information raised awareness about the symptoms

of HDP and when to report to health care professionals (4/11). Some interview participants (2/11) argued that these insights are paired with responsibilities to carefully measure blood pressure and to contact the health care professional when symptoms increase.
A second aspect related to patient autonomy mentioned by participants was that the use of mHealth contributed to them being in control of their own health and to bring their own perspectives to the fore in consultations with health care professionals (7/11). mHealth allowed them to monitor their own symptoms and, when necessary, adapt their behavior (4/11), for example with regard to activities or medication (P8, Table 4).

Theme 4: Health Care Professionals' Expertise and Responsibilities

Quantitative Analysis

After starting the digital monitoring, it was clear for the majority of the participants when the digital monitoring team needed to receive their measurements (49/51, 96%) and when to contact the physician regardless of their data (42/51, 82%). They felt that their personal wishes were sufficiently considered by the health care professionals (46/52, 89%). Most of the survey respondents said they could tell that their obstetric care professional really listened to them (50/52, 96%) and that they were given enough opportunity to say what kind of care they needed (47/52, 90%).

Qualitative Analysis

In addition to the findings of the quantitative research, interviewees showed that they consider the expertise of the health care professionals important in monitoring HDP. All interview participants (11/11) said that health care professionals have invaluable clinical expertise to oversee the implications of the measurements, as well as to decide the need for additional tests, the interval of clinical visits, and medication or hospitalization. The follow-up initiated by health care professionals — either by phone or via clinical visits — contributed to the feeling of being well taken care of and met the interviewees' expectations regarding responsibilities (5/11). Patients also mentioned that it should remain the health care professionals' responsibility to undertake action when the measurements deviate from the norm (5/11). They felt relieved that monitoring and resulting action are not solely the patient's responsibility (11/11). Moreover, patients were appreciative that health care professionals acted if a patient would underestimate the severity of their situation (3/11). Patients argued that important decisions about their condition cannot exclusively be based on the information from the tool, but an expert's clinical view is required for interpretation and to make personalized treatment decisions (5/11; Table 5).

Table 5. Quotes illustrating interviewees' perspectives on expertise and responsibilities of health care professionals.

Topic	Quotes
Medical expertise	Well, for me, those data, I'm not trained as a health care professional, to interpret my data. I, myself, had the [possibility] to see how my blood pressure developed over time. But the idea that health care professionals see my data and can interpret it and can ask you to come to the hospital when necessary, that is comforting. (P2)
	[..] and that they can interpret it. Like for me, it was the case that it [blood pressure] was higher than 90, even if 90 is the threshold value for me, but [they explained] that for me, you see sometimes other things happening. Then I know that, you know, it's very helpful when a physician helps me and interprets the data. I mean, that they don't simply tell and stick to the threshold values, but also interpret it in your specific situation. I believe the shared effort lies in me conducting the measurements and supplying that information. (P8)
	[..] it's a shared effort. But I think the physician is leading because they know best. I mean, I know more or less which medication I take now and what sort of effect it has on me. But I don't know, for example, whether or when I can stop taking medications and what consequences it would have; I haven't studied for that. (P4)
Active monitoring	I really like having been called after [by a nurse], because then you have confirmation that they will undertake action when it is necessary. [..] I think it was great, that in that way also really something is done with the data you collect every day. (P7)

DISCUSSION

This study analyzed user experiences with a blended care approach for the monitoring of HDP (SAFE@HOME study). Overall, the results of the questionnaires and interviews corresponded and were supplementary. The effects of using mHealth met the expectations of the participants, who were overall very satisfied with the easy-to-use technology. mHealth was considered to support patient autonomy by providing information and ways to be in control, but the interpretation of the measurements requires the involvement of health care professionals. Participants also noted a few possibilities for improvement.

With the focus on future development and implementation of mHealth in care, we extracted multiple recommendations from our results:

1. Be modest in the communication regarding expected group benefits of the digital health technology to prevent disappointing individual patients who do not experience these specific benefits.
2. Provide the user insight into the data; in particular, a graphic representation over time is a helpful method to foster patient knowledge and can support patients to participate in clinical decision making.
3. The mHealth data should be integrated in (electronic) health records and should be accessible to all health care professionals that are engaged in care.
4. The health care professionals should remain responsible for the interpretation of data obtained via digital monitoring, as the clinical expertise of health care professionals is necessary for the early detection of abnormalities and clinical decision making.
5. Health care professionals should be aware of (pregnant) patients' willingness and capability to self-measure their blood pressure at home.
6. Symptom score lists and blood pressure thresholds should be personalized, meaning that the questions should be adapted to the pregnancy term and thresholds should be set to fit the user's situation.
7. The moment and frequency of measurement should be communicated clearly but should also be sensitive and adaptable to the daily life of the user.

Our Findings in Context

Currently, several digital technologies are being developed that moderate or replace traditional clinical care. The study described here is an excellent example of such digital health technology in the clinical context that replaces some of the care traditionally provided in the clinical setting with digital monitoring at home. Our study confirmed several findings described by other digital monitoring studies. Some comparable studies have reported on remote blood pressure monitoring in pregnancy, without in-clinic monitoring by care professionals.[21,22] For a comparable intervention with clinical monitoring, only survey data

were reported.[15] Our study confirmed that pregnant women at risk of HDP are willing to participate in self-monitoring services and are capable of bearing the responsibilities of measuring their own blood pressure.[15,21,22] Our study confirmed that women who experienced HDP in a prior pregnancy, in particular, were strongly in favor of blended care approaches in prenatal care.[22] A comparable intervention for pregnant women with hypertension that included remote monitoring of blood pressure and monitoring by health care professionals reported that 83% of the participants experienced a feeling of safety and that 68% preferred to be contacted within 12 hours after the measurement in case of abnormal measurements, preferably by their midwife or obstetrician.[15] Our study found comparable feelings of appreciation and safety among the users, partly because of the follow-up by health care professionals by phone or via clinical visits. Self-measuring was found to be reassuring; when abnormal values were detected as women took and interpreted their own measurement, it was clear for the participants when to contact the clinic.[21] Other studies have also found that women prefer that blood pressure monitoring should not stop at the delivery date, but should be available postnatally, which was also expressed by our interview participants.[21,22]

Opportunities for and Challenges With Blended Care Approaches in Clinical Care

With the rapid development and implementation of digital technologies in health care settings, the need for ethical guidance and practical recommendations for the implementation of such technologies, including mHealth, is widely acknowledged by patients, health care professionals, and influential advisory councils.[23-25] With the implementation of these technologies, it becomes possible to move beyond mere speculative debates about the opportunities and challenges of mHealth and to investigate how the practice is developing. Our study explored both user experiences and the expectations of users prior to using mHealth tools for digital monitoring. User experiences depend not only on the quality of the technology but also on the expectations one has before using it. Investigating both expectations and experiences is helpful, not only to understand what may motivate pregnant women to use such technologies but also to assess whether these tools live up to users' expectations. Our study provides several insights in that respect: less frequent hospital visits and better-informed patients were often mentioned as factors contributing to the satisfaction with this technology. This shows that some of the widely discussed promises of mHealth were met in our study. Other claims about mHealth, such as increased accessibility, cost-effectiveness, and more empowered patients[1,2], were not (fully) substantiated by our study.

Furthermore, our study indicates that ethical guidance for the use of digital technologies in health care settings differs in significant ways from concerns about digital health consumers. Using digital technologies, including mHealth, in health care settings raises a wider range of ethical challenges than have been described in the consumer context.[26,27] Aside from concerns about effectiveness, privacy, and safety, the health care context requires us to carefully assess the delegation of responsibilities to patients, influence on patient autonomy,

and proportionality of burden and benefits. Regarding the delegation of responsibilities, our study showed that users are able to bear the responsibility for measuring their own blood pressure, but they did not feel able to bear the responsibility of interpreting their own data. Clinicians play an important role in the responsible use and implementation of these technologies. This indicates that careful consideration is required regarding which tasks and responsibilities can be delegated to technology (instead of face-to-face care) and which can be delegated to patients (instead of the health care professionals) without compromising safety or quality of care. Digital technologies, including mHealth, are not a stand-alone solution in the clinical context and need to be supplemented with clinical expertise. With regard to the influence on patient autonomy, our study has supported evidence that patients can become more familiar with their own body and disease symptoms and are able to use this information in adjusting their behavior or to deliberate with physicians. It is important to recognize that supporting and respecting patient autonomy are not completely in their own hands. Health care professionals involved in blended care play a crucial role. Not only will health care professionals have to recognize and respect wishes of autonomous persons but will also have to navigate between the standardized way of measuring, supported by digital technology, while still being able to personalize the analysis and interpretations to the interests and needs of a specific patient. Lastly, while mHealth technologies have several benefits, such as accessibility of information for both patients and health care professionals, less frequent hospital visits, and better understanding of one's own conditions, these benefits need to outweigh the burden of using these technologies (eg, time investment, user friendliness). Overall, our participants were very positive and satisfied with the mHealth technology, but the interview participants who felt their blood pressure was stable because of prescribed medication argued that the burden of measuring every day became somewhat disproportionate. Less frequent measurements may be a way to balance the burden and benefits for these groups. It also indicates that high levels of satisfaction with this blended care approach might be specific to the high-risk population that was selected for this approach. For the high-risk population, there is much to gain in terms of both health outcomes and time investment, but the balance may tip differently for medium-risk to low-risk groups.

Strengths and Limitations

This is a mixed-methods study that benefits from reducing weaknesses inherent to both methods; it expands understanding, while also being comprehensive. Approximately half of the total users of the mHealth technology filled out the validated questionnaires. The sample of interviewees was representative of the participants of the questionnaires in terms of age, BMI, education level, and underlying conditions (Table 1). The findings of the survey and interviews were supplementary and helped to better understand what and for which reasons the mHealth tool was appreciated, which can inform future mHealth health interventions.

Our results must be interpreted in the context of the following limitations. Selection bias

(self-selection) might have influenced the results, as participants of the prospective study agreed to take part in this innovative strategy with digital monitoring and may thus have a positive attitude in general to mHealth. Furthermore, the women willing to participate in this study may have had a relatively positive experience with this specific technology. Also, the experience of participants could have been biased by the outcome of their pregnancy. However, as the findings of the questionnaires (collected during pregnancy) and the interview data (8 postpartum, 3 during pregnancy) correspond, the influence may be marginal. The interviewed patients were fairly highly educated and may therefore not be representative of pregnant women in other socioeconomic situations. This explorative study has a relatively small sample size; in both the quantitative and qualitative aspects of the study, the provided ratios and percentages were not statistically powered and therefore cannot be fully generalized to other populations or care settings. Although saturation was reached on the identified codes and themes, further research could investigate these topics in more depth.

Conclusions and Recommendations

Our study explored the perspectives of pregnant women regarding the use of mHealth in a blended care approach to remotely monitor blood pressure in pregnancy. Based on the experiences of the users, several recommendations have been formulated. These recommendations draw on the needs, experiences, and views of the patients, meaning that following these recommendations will contribute to better-aligned and patient-centered care. These recommendations can help other scholars or physicians to guide the process of implementation and design of similar mHealth technologies.

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Multimedia Appendix 1– client-centered-care questionnaire (CCCQ) Participants n=52

1.1 I can tell that the carers take my personal wishes into account.

1 – strongly disagree	Number (%)	0 (0%)	
2 – disagree	Number (%)	0 (0%)	
3 – neither disagree nor agree	Number (%)	6 (11.5%)	
4 – agree	Number (%)	34 (65.4%)	46 (88,5%)
5 - strongly agree	Number (%)	12 (23.1%)	

1.2 I can tell that the carers really listen to me.

1 – strongly disagree	Number (%)	2 (3.8%)	
2 – disagree	Number (%)	0 (0%)	
3 – neither disagree nor agree	Number (%)	0 (0%)	
4 – agree	Number (%)	38 (73.1%)	50 (96,1%)
5 - strongly agree	Number (%)	12 (23.1%)	

1.3 I can tell that the carers take into account what I tell them.

1 – strongly disagree	Number (%)	1 (1.9%)	
2 – disagree	Number (%)	3 (5.8%)	
3 – neither disagree nor agree	Number (%)	1 (1.9%)	
4 – agree	Number (%)	33 (64.5%)	47 (90,4%)
5 - strongly agree	Number (%)	14 (26.9%)	

1.4 I get enough opportuniy to say what kind of care I need.

1 – strongly disagree	Number (%)	0 (0%)	
2 – disagree	Number (%)	1 (1.9%)	
3 – neither disagree nor agree	Number (%)	4 (7.7%)	
4 – agree	Number (%)	32 (61,5%)	47 (90,4%)
5 - strongly agree	Number (%)	15 (28.8%)	

1.5 I can tell that the carers respect my decision even though I disagree with them.

1 – strongly disagree	Number (%)	0 (0%)	
2 – disagree	Number (%)	0 (0%)	
3 – neither disagree nor agree	Number (%)	22 (42.3%)	
4 – agree	Number (%)	22 (42.3%)	30 (57,7%)
5 - strongly agree	Number (%)	8 (15.4%)	

1.6 In my opinion the carers are clear about what they are able and allowed to provide.

1 – strongly disagree	Number (%)	0 (0%)	
2 – disagree	Number (%)	1 (1.9%)	
3 – neither disagree nor agree	Number (%)	7 (13.5%)	
4 – agree	Number (%)	30 (57.7%)	44 (84,6%)
5 - strongly agree	Number (%)	14 (26.9%)	

1.7 In my opinion the carers are sometimes too quick to say that something is not possible.

1 – strongly agree	Number (%)	1 (1.9%)	
2 – agree	Number (%)	6 (11.5%)	
3 – neither disagree nor agree	Number (%)	15 (28.8%)	
4 – disagree	Number (%)	20 (38.5%)	30 (57,7%)
5 - strongly disagree	Number (%)	10 (19.2%)	

1.8 I'm given enough opportunity to use my own expertise and experience with respect to the care I need.

1 – strongly disagree	Number (%)	0 (0%)
2 – disagree	Number (%)	2 (3.8%)
3 – neither disagree nor agree	Number (%)	10 (19.2%)

4 – agree	Number (%)	28 (53.8%)	40 (76,9%)
5 - strongly agree	Number (%)	12 (23.1%)	

1.9 I'm given enough opportunity to do what I am capable of doing myself.

1 – strongly disagree	Number (%)	0 (0%)	
2 – disagree	Number (%)	0 (0%)	
3 – neither disagree nor agree	Number (%)	5 (9.6%)	
4 – agree	Number (%)	38 (73.1%)	47 (90,4%)
5 - strongly agree	Number (%)	9 (17.3%)	

1.10 I'm given enough opportunity to help decide on the kind of care I receive.

1 – strongly disagree	Number (%)	0 (%)	
2 – disagree	Number (%)	1 (1.9%)	
3 – neither disagree nor agree	Number (%)	8 (15.4%)	
4 – agree	Number (%)	31 (59.6%)	43 (82,7%)
5 - strongly agree	Number (%)	12 (23.1%)	

1.11 I'm given enough opportunity to help decide on how often I receive care.

1 – strongly disagree	Number (%)	1 (1.9%)	
2 – disagree	Number (%)	2 (3.8%)	
3 – neither disagree nor agree	Number (%)	15 (28.8%)	
4 – agree	Number (%)	22 (42.3%)	43 (82,7%)
5 - strongly agree	Number (%)	12 (23.1%)	

1.12 I'm given enough opportunity to help decide on how the care is given

1 – strongly disagree	Number (%)	1 (1.9%)	
2 – disagree	Number (%)	4 (7.7%)	
3 – neither disagree nor agree	Number (%)	13 (25.0%)	
4 – agree	Number (%)	25 (48.1%)	34 (65,4%)
5 - strongly agree	Number (%)	9 (17.3%)	

1.13 I have a say in deciding on when carers come to help me.

1 – strongly disagree	Number (%)	3 (5.8%)	
2 – disagree	Number (%)	11 (21.2%)	
3 – neither disagree nor agree	Number (%)	17 (32.7%)	
4 – agree	Number (%)	17 (32.7%)	21 (40,4%)
5 - strongly agree	Number (%)	4 (7.7%)	

1.14 In my opinion, I am consulted sufficiently on who provides the care.

1 – strongly disagree	Number (%)	1 (1.9%)	
2 – disagree	Number (%)	9 (17.3%)	
3 – neither disagree nor agree	Number (%)	13 (25%)	
4 – agree	Number (%)	24 (46.2%)	29 (55,8%)
5 - strongly agree	Number (%)	5 (9.6%)	

1.15 I'm given enough opportunity to arrange and organize the care provided myself.

1 – strongly disagree	Number (%)	1 (1.9%)	
2 – disagree	Number (%)	8 (15.4%)	
3 – neither disagree nor agree	Number (%)	17 (32.7%)	
4 – agree	Number (%)	23 (44.2%)	26 (50,0%)
5 - strongly agree	Number (%)	3 (5.8%)	

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PART II

TELEMONITORING OF PREGNANT WOMEN WITH COMPLICATIONS IN PREGNANCY

CHAPTER 8

HOME-BASED TELEMONITORING VERSUS HOSPITAL ADMISSION IN HIGH RISK PREGNANCIES: A QUALITATIVE STUDY ON WOMEN'S EXPERIENCES

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ABSTRACT

Background

Hospital admission during pregnancy complications is considered to be an event of significant impact. Besides conventional in-clinic maternal and fetal monitoring, recent technologies enable home-based telemonitoring with self-measurements in high risk pregnancy. This study is part of a feasibility pilot to explore the usability and acceptability of telemonitoring and aims to gain insight in the experiences and preferences of high risk pregnant women concerning the novel strategy of telemonitoring, opposed to women who were hospitalized in pregnancy.

Methods

Using secured Facebook Groups, we conducted four online focus groups: two focus groups with women who were admitted during pregnancy (n=11) and two with women who received home telemonitoring in the pilot phase (n=11). The qualitative data were analyzed thematically.

Results

Four major themes emerged from both participant groups: (1) care experience, (2) emotions regarding pregnancy, (3) privacy and (4) impact on daily life. Different views were reported on all four themes, resulting in a direct comparison of experiences during hospitalization and telemonitoring. Most admitted patients reported a growing sense of boredom and anxiety during their clinical admission. Lack of privacy on ward was a great concern, as it affected their contact with hospital staff and family. This issue was not reported amongst telemonitored women. These participants still felt like a patient at times but responded that the comfort of their own home and bed was pleasant. Only a minority of telemonitored participants reported being anxious at times at home, while not having a physician or nurse nearby. Being at home resulted in less travel time for partners or family for hospital visits, which had its positive effects on family life.

Conclusions

Telemonitoring of a high-risk pregnancy provides an innovative manner to monitor fetal and maternal condition from home. Compared to the experiences of hospital admission in high risk pregnancy, it allows women to be in a comforting and private environment during an anxious time in their lives. As future studies should further investigate the safety and cost effectiveness of this novel strategy, women's views on the preference of telemonitoring need to be taken into consideration.

INTRODUCTION

Worldwide, the number of women at increased risk for complications in pregnancy continues to grow due to unhealthy lifestyle, obesity, advanced maternal age at conception and concurrent comorbidities.[1-3] High-risk pregnancy is defined as any pregnancy in which there is a factor—maternal or fetal— that potentially acts adversely to affect the outcome of pregnancy, for example preterm rupture of membranes (PROM), fetal growth restriction (FGR) and preeclampsia (PE).[4] International guidelines recommend increased monitoring and observation of maternal and fetal parameters, which essentially leads to hospital admittance. [5-7]

Hospital admission during pregnancy is considered to be an event of significant impact, because of combined stressors of both pregnancy and hospitalization.[8] In previous quantitative studies on hospitalization during high risk pregnancy, women report lower self-esteem, greater anxiety and depression and less optimal family functioning.[9] Experienced fear, anxiety for the unknown and perceived immobility and inactivity are amongst stressors and emotions during hospitalization.[10-12]

Besides conventional care during clinical admission, recent technological advances resulted in e-Health, defined as health services and information delivered or enhanced through the Internet and related technologies. Potential positive effects of the use of these forms of e-Health include increased patient engagement and satisfaction, better access to health care and the possibility to reduce clinic costs with equal or better health outcomes.[13 14] e-Health has already found its way in perinatal care and its implementation is likely to disperse globally in the next decade.[15]

Telemonitoring of fetal heart rate combined with uterine contractions in complicated pregnancies is possible with help of a wireless portable cardiotocography (CTG) system combined with a blood pressure monitor. Measurements from home are saved in a personal profile using Bluetooth. Through a secured internet portal, data are integrated in the electronic patient record system making access possible for health care professionals. In recent years, several comparable systems for remote monitoring of maternal and fetal condition have been developed and found feasible with regards to usability, acceptability and clinical usefulness.[15] As an addition to prenatal care, telemonitoring can result in increased adherence to appointments, reduced clinic visits and enhanced patient engagement.[15] However, safety of use for perinatal outcomes of these digital telemonitoring platforms has not been studied extensively in high-risk pregnancy. As an essential component in the quality of health care, patients' involvement in the development and implementation of e-Health strategies gives relevant information to improve the use in daily practice.[16]

This study aimed to assess the experiences of pregnant women during clinical hospital admission and the novelty of telemonitoring during high risk pregnancy.

METHODS

This qualitative study using online focus groups was designed as part of a pilot study for telemonitoring in high risk pregnancy. Aim of the feasibility pilot was to examine the accuracy of the tracings, the system's usability and participants' experiences and acceptance. In this paper we report women's experiences of telemonitoring during the pilot.

Context of the feasibility pilot

Wireless devices for blood pressure (Microlife WatchBP) and cardiotocography (Sense4Baby, BMA- Telenatal, The Netherlands) were used for daily follow up of patients with either PPROM, FGR or preeclampsia.[17 18] Following a hospital admission for initial observation and treatment (e.g. antenatal corticosteroids), admitted patients were reviewed by the supervising obstetrician for eligibility for telemonitoring until start of labor. Selection criteria were 1) singleton pregnancy (for technical reasons), 2) travel time from home to the hospital within 30 minutes, 3) the ability to understand the devices and perform measurements as prescribed and 4) no complications requiring i.v. medication or obstetric intervention within 48h (e.g. severe hypertension, signs of infection or antepartum hemorrhage). After instructions by a member of our centre's Obstetric Telemonitoring Team (consisting of a clinical midwife, the resident on ward supervised by an obstetrician), participants performed their daily CTG and blood pressure before 9.30 AM. Each morning, a member of the Obstetric Telemonitoring Team reviewed the measurements and contacted her at home to ask for symptoms, discuss the results and future management. At least once a week participants visited the outpatient clinic for clinical review. In case of abnormal results (e.g. non reassuring CTG, increase in blood pressure or symptoms of hypertensive disease or infection) patients were admitted to the ward for further evaluation.

Design

We set up online focus group (FG) discussions in secured Facebook groups within two different groups: one group of women who were admitted to the hospital during pregnancy and one group of women who were monitored at home (using home-based telemonitoring, TM).

Conducting online FG is practical to women with young children, because of the possibility to react at any time of the day while there is no time needed to travel.[19] Also, the perceived anonymity of online communication lowers social inhibitions that might hold back participants in a real-time FG. Facebook in particular is a convenient platform for an online FG, because participants are familiar with its interface, the Group function facilitates notifications, tags and commenting on comments. The Secret Group function enables privacy as participating is only possible for invitees.[20]

Our FGs were conducted following a semi-structured interview protocol including open ended questions on topics that were defined after literature review and expert opinion. These included: experiences of received health care, personal feelings and family life. The groups were open to the participants and one moderator only [both research physicians, JH (male) or CT (female), trained by experienced researchers using Facebook focus groups]. The moderators did not establish a relationship with the participants before study start,

expect for their occupation as researchers in the obstetric department focusing on home monitoring in pregnancy. Each focus group was open for five days, and two questions were posted on Facebook daily to which all women were invited to comment. When needed, the moderator commented in response to help the discussion along. All questions that were posted in the Facebook groups can be found in Supplemental file 1.

Ethical approval

This study was exempted from approval of the Medical Research Ethics Committee of the University Medical Center in Utrecht (reference number 16-203), as the Committee confirmed that the Dutch Medical Research Involving Human Subjects Act (WMO) did not apply to this study.

Sampling and Recruitment

Two different groups of women were approached by phone at 6 weeks postpartum through purposive sampling. The first group consisted of women who had been admitted to our hospital for PPROM, FGR or preeclampsia, and who gave birth before the start of the telemonitoring pilot. The second group consisted of women with one of the same three complications, but who went home to receive telemonitoring during the pilot phase. Eligible candidates for the FGs had to be >18 years, with singleton pregnancy and good ability to understand Dutch language. Those women interested in participation received written information by mail, including an informed consent form, the schedule for the study and additional information about Facebook and privacy settings. Candidates were able to ask question about the study prior to their decision to participate.

Data collection & Privacy

After informed consent, we provided additional information on how to join the discussion in a private Facebook group. All comments were saved using codes for data analysis. When the research group agreed that saturation had been reached, recruitment was stopped. Afterwards all comments were manually removed by the moderator and the Facebook groups were shut down.

Data analysis

Each step of data analysis, using an iterative and inductive process, was performed independently by JH and CT. Questions and responses were processed manually into transcripts using open coding, assigned to text fragments. After this, the initial codes were combined as they functioned as subcategories within a broader theme. Both researchers discussed the codes and grouping together ensuring accuracy of interpretation. This resulted in four themes, with three of them divided into subcategories (See Figure 1):
(1) experience with obstetric care,
(2) feelings regarding pregnancy,
(3) privacy and
(4) impact on daily life,
Representative quotes for the different themes were selected and translated into English.

Figure 1. Four main themes and their subcategories resulting from the focus groups

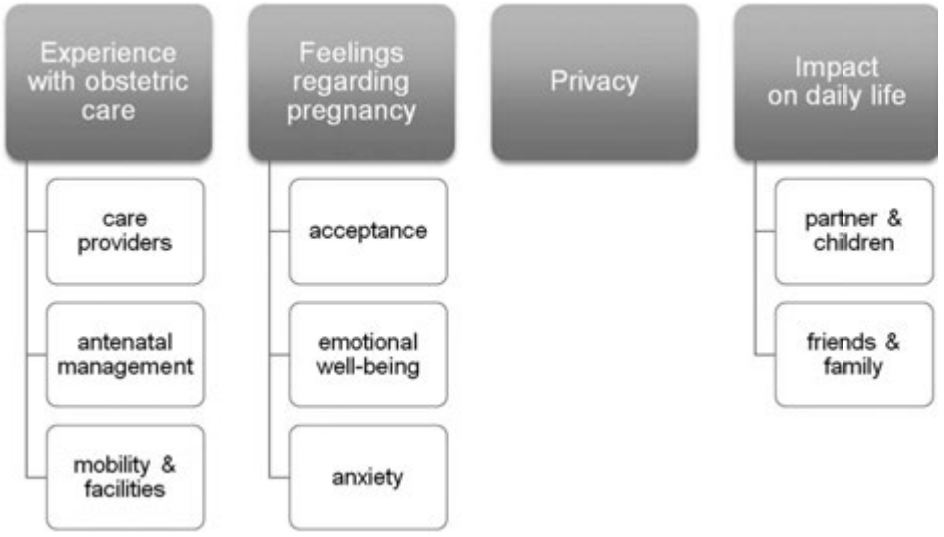

Table 1. Participant characteristics

		Hospital admission (n = 11)	**Telemonitoring (n = 11)**
Age; mean (SD)		30.6 (6.6)	32.1 (5.0)
Nulliparous; n (%)		8 (72.7)	7 (63.6)
Dutch origin [a]		9 (81.8)	8 (72.7)
Educational level [b]	Low	2 (18.2)	2 (18.2)
	Intermediate	3 (27.2)	2 (18.2)
	High	6 (54.5)	7 (63.6)
Diagnosis; n (%)	PPROM	4 (36.4)	1 (9.1)
	FGR	3 (27.2)	7 (63.6)
	PE	4 (36.4)	3 (27.2)
Length of monitoring in days, mean (SD)		17.9 (14.9)	15.8 (12.2)
Length of monitoring in days; range		7-60	7-49

Legend: PPROM, preterm rupture of membranes; FGR, fetal growth restriction; PE, preeclampsia

[a] Both parents born in the Netherlands (Dutch National Office of Statistics)

[b] Education was defined as 'low' (elementary school, lower level of secondary school), 'Intermediate' (higher level of secondary school) and 'high' (post-secondary and university)

RESULTS

Of 42 women approached, 22 women consented to participate. Reasons not to participate in the online study were: no response to the invitation, busy family life at six weeks postpartum, lack of Facebook account or not willing to join Facebook. We conducted four focus groups: two with participants with hospital admission in pregnancy (HA, total n=11) and two with participants with telemonitoring experience in pregnancy (TM, total n=11). Participant characteristics are shown in Table 1. Average length of hospital stay during admission was 17,9 days (range 7-60), average length of telemonitoring was 15,8 days (range 7-49).

Hospital Admission group

1) Experience with obstetric care

Recalling their admission, half of the admitted group (6/11) was pleased with the explanation they received from the residents on ward about management and prognosis during admission. Contrarily, the others (5/11) missed coherent and straightforward management prior to their delivery, because the turnover of involved residents and obstetricians was perceived as very high during admission.

> *[HA10] "The general approach of management was clear to me, although it changed multiple times during admission."*
> *[HA20] "... in my experience the different residents on ward constantly came up with conflicting information despite the explanation from our own 'case manager' [consultant obstetrician]. However, because I was admitted, it felt like contact with our case manager ceased over time, resulting in unnecessary stress and uncertainty."*

Opinions about nurses, midwives and physicians during admission were predominantly positive. The personal approach of the nurses was highly praised, stating that questions about medical or personal issues were always possible. However, 4/11 participants addressed their concerns about the many changes of shift, causing distrust when seeing new faces every day.

> *[HA07] "I was admitted during a week-end and even then we could talk to a physician and a midwife, which was very pleasant for my partner and me. The nurses were always available for a little chat."*
> *[HA12] "I had the feeling that there were many changes in residents and physicians (...) That's why I felt the need to be watchful regarding my own management during admission."*

Hospitalization often comes with restrictions in personal time and mobility, sometimes imposed by physicians, being physically bound to bed by monitors or catheters. Three

participants in the hospital group remembered being in bed for hours for non-stress tests (cardiotocography), which was physically and mentally straining. The restrictions on their activity made some women very restless.

> *[HA11] "I had to stay in bed or a wheelchair most of the time. Although I knew this was for the better for the baby, it was still hard on me."*

The facilities in the hospital generated mixed reviews. Some positive remarks were made concerning the private bathrooms, television and internet, but most negative remarks were made regarding the food and beds – most of the participants missed their personal habits and choices for dinner.

2) Feelings regarding pregnancy

The majority of patients in the hospitalized group accepted the need for daily monitoring and admission, although some participants (3/11) argued that they could have stayed at home, since they did not experience any physical complaints themselves. Being confronted with pregnancy complications was mostly followed by emotions of fear, anger and sadness.

> *[HA07] "We instantly understood why I had to stay in the hospital. After this, it like felt we stepped into an emotional rollercoaster… anxious, angry, sad but also relieved and happy."*

Most of the participants in the hospital group felt bored or isolated. In some cases, boredom resulted in agitation or frustration, not knowing when or how this specific situation would end. The longer the admission lasted, the more the boredom would strike, as 4/11 subjects addressed.

> *[HA09] "Later on, the boredom just intensified. It felt disturbing. Every day passed by in the same way. I could never go somewhere. Reading and watching television is only amusing for a while, but not the whole day, each and every day."*

The presence of anxiety and fear is associated with the uncertainty of the future health of their babies or their own body. Admitted participants felt more anxious as the admission continued, since they heard more about the risks associated with high risk pregnancy. Worrisome results of ultrasounds, cardiotocography or blood tests altered these feelings of fear. On the contrary, experiencing calm periods in the hospital, or hearing promising results of antenatal tests was beneficial. One participant [HA11] raised the concept that her stay in the hospital felt safe, "… knowing that personnel was close by and able to react quickly in acute situations."

3) Privacy

In the hospitalized group, the subject of privacy generated strong reactions during our study. As the ward is a relatively public area, staff, other patients, their family, friends can move in and out of the room at almost every time of the day. This interfered with personal routines and privacy.

> *[HA19] "I really missed my privacy. Anyone in my room could overhear the chats I had with family and friends, which was really annoying."*
> *[HA21] "There was a lack of privacy. While overhearing everything my 'roommate' said, she could also hear my talking. I didn't feel comfortable while talking to the doctors while she was in the room. Visits of my partner didn't really feel like we were there together."*
> *[HA09] "How would you feel if everything you discuss with your doctor, can be heard by all your roommates on ward? I didn't want to share all this personal information with strangers."*

A discussion arose on the positive and negative sides of rooms shared with multiple patients. Half of the hospitalized group felt they found support in contact with their roommate. Others were bothered with their neighbors and their visitors, only divided by a curtain.

> *[HA19] "A curtain doesn't mean there is any privacy. I missed having personal conversations with family. But the last two days I was in a private room and I missed the amusement and relaxation of being with other patients. A compromise would be great."*

4)Impact on daily life

The need for support from loved ones was mentioned several times by the admitted patients. Although family members and friends were able to visit the ward, the impact on them is not to be underestimated. Partners often worked normal working hours during admission and spent much time traveling to and from the hospital, which felt difficult and tiresome. Pregnant women missed spending time with their other children and partners.

> *[HA08] "It had a big impact on my two-year-old son. We had never been separated before and saying goodbye to him was hard, every single day. It was also hard on my partner. He suddenly had to take care of our child on his own, take time off from work and drive to the hospital, sometimes 2-3 times a day."*

Telemonitoring group

1) Experience with obstetric care

The home-based telemonitoring started with an elaborate explanation of the care-pathway and the use of the monitoring equipment. The devices were easy to use and participants had no to very little technical issues. The daily results and plans for future antenatal management were discussed by phone by the Obstetric Telemonitoring Team members.

> *[TM03] "…[the midwife] explained the use of the equipment and took us through all the steps of the entire process. For me it was really nice to speak to somebody on the phone every single day. In my experience they would call quickly after sending the CTG and they would take the time to answer all of my questions."*

The weekly appointments in the outpatient clinic during TM were often appreciated (7/11), although, some women experienced getting back and forth from the hospital as a hassle. All highly valued the daily contact with the Obstetric Telemonitoring team, primarily midwives. By telephoning each day, they had the chance to ask their questions and be reassured if needed. The clinical midwives of the Obstetric Telemonitoring Team were often described as 'empathetic' and 'very competent'.

> *[TM01] "I really appreciated the daily phone calls, and when things got to my head, the midwife functioned as a sympathizing listener (…) They were really helpful."*

In general, mobility did not seem to be a pressing issue for the women at home, even though some of the women were told to rest as much as possible. Being home-based, all the women agreed that sleeping in their own bed was much more comfortable than a hospital bed, waking up well- rested. Those women, who were admitted first and subsequently received telemonitoring, added that the noises on ward during night had profound impact on their sleep, which was not the case at home.

2) Feelings regarding pregnancy

In general, all of the telemonitoring women agreed that the indication for daily monitoring was clear. Again, the complications caused feelings of uncertainty, anxiety and restlessness.

> *[TM05] "We understood the reasons for all the extra assessments during pregnancy. It gave us a safe and reassuring feeling, knowing that somebody kept an eye on the baby on a daily basis, and that our concerns were taken seriously. "*
> *[TM03] "I am very happy that I didn't need to stay in the hospital for weeks, but that I was offered telemonitoring instead."*

The women in telemonitoring enjoyed being at home. They expressed being at home was more peaceful and calm then being admitted at the hospital. Even though these women were not admitted in a hospital, they were very well aware that their pregnancy was complicated.

[TM03] "Because I had to stop working during the 30th week of my pregnancy, as I had to monitor myself every morning, I felt like a high-risk patient."

Only 2 out of 11 women from this group expressed anxious episodes at home. In these two subjects, anxiety was related to the realization of being alone when trying to do the correct monitoring or the need to come to the hospital for further evaluation. This uncertainty sometimes caused concern about what was going to happen next.

[TM07] "Yes, sometimes I would have preferred to have a doctor nearby, for example if I could not find the fetal heart rate with the monitor or when I did not feel the baby move for quite a while."

[TM16] "I enjoyed being at home; it was a lot better than being in the hospital (…) I had to return to the hospital multiple times because of my blood pressure or a questionable CTG. Each time this happened, I had to wait and see if I could go back home. This made me feel like a high risk patient, although much less then when I was admitted to the hospital."

3) Privacy

In contrast to the hospital based participants, none of the women in the telemonitoring group reported issues regarding privacy.

4) Impact on partner and/or family

Being at home resulted in less travel time for partners or family for hospital visits, which had its positive effects on family life. Some women in the telemonitoring group had help at home: family would help out with errands, house cleaning or taking care of other children. One woman [TM2] pointed out that, having a toddler around, resting at home was not always easy.

[TM1] "Daily life just continued when I was at home, for both me and my family... In the morning, I sent the CTG, and I rested a little more than I would normally do, because of my blood pressure."
[TM2] "Home monitoring was much more relaxed to me, compared to my first pregnancy when I was admitted in my 29th week. Now I could stay with my little son, very important for both his comfort and mine."

DISCUSSION

The aim of this qualitative study was to compare the experiences of high risk pregnant women during hospital admission or telemonitoring. Although the uncertainty of high risk pregnancy remains an intense experience for both women and their families, telemonitoring seems to allow them to experience this considerably less stressful compared to hospital admission.

Complications of pregnancy come with feelings such as fear and frustration, especially while being admitted to the hospital. As antenatal anxiety and depressive symptoms are common among obstetric inpatients, they increase the risk of post partum depression and adversely affect infant and child development.[21] The hospital admission group in our study reported a growing sense of boredom and anxiety during their admission, which is in line with earlier work on hospitalization during pregnancy: women report concerns for the health of their future baby, feeling of helplessness and loneliness while being separated from home, family and friends.[10-12] Lack of privacy, when admitted, affected our patients' contact with health care providers, partner, kids (if present) and other family and friends. In contrast, the experiences at home in our telemonitoring group were more positive: although they still felt like a patient at times, the TM group responded that the comfort of their own home and bed was very pleasant. In this group, only a minority of participants reported being anxious at times at home, while not having a physician or nurse nearby. Findings from our and previous studies reveal that telemedicine could provide important psychological benefits during pregnancy.[22] When women's perception of high risk pregnancy and quality of care experience improve with telemonitoring, this may contribute to an increase in quality of life and reduction of antenatal anxiety and its consequences for mother and child.

O'Brien et al. and Rauf et al. described the experiences of remote fetal monitoring during outpatient induction of labour in a low risk pregnancy group in 2009-2010.[23,24] Their study made use of wireless fetal-maternal monitoring device for remote non-invasive trans-abdominal monitoring of fetal heart activity, and electromyography for uterine activity. The participants concluded that telemonitoring during induction offered them freedom and familiarity of home environment, but feelings of reassurance depended on effective communication with hospital staff. These observations are in line with our findings, as our participants reported a positive effect of staying at home while being monitored daily by familiar midwives within the Obstetric Telemonitoring Team, opposed to tridaily changes in hospital staff on maternity ward.

The experiences of our telemonitoring group correspond with trends of eHealth use in perinatal care: women of reproductive age are interested in e-Health, because of their

frequent use of smartphone, apps, and online searches for pregnancy education.[15] Literature reviews conclude that health outcomes for eHealth interventions in perinatal care are generally positive, resulting in lifestyle and mental health improvement or providing multiple other advantages while health outcomes were found equal (e.g. in gestational diabetes). [15 25 26]

Social changes are demanding a shift to home-based patient-centered care, and remote monitoring provides flexibility to both physicians and patients to decrease the demand for more hospital personnel or clinic space.[27] Both groups embrace telemedicine because of its usability, tendency to improve access to care, communication and outcomes while decreasing clinic visits and travel time.[11] These changes are assumed to have profound cost-saving effects in favor of telemonitoring, an important aspect regarding the ever-increasing health care costs – and workloads.[14] Compared to usual care, possible additional time associated with telemonitoring (instructions for patients, daily telephone contact, and weekly outpatient visits) should be explored in cost-effectiveness studies. Organizations will potentially benefit from telehealth as it decreases missed appointments, waiting times and re-admissions, although reimbursement lacks to progress due to legislation and swift technological advancements.

Implementation of (fetal) telemonitoring in pregnancy is not studied extensively, and further research is needed on the effectiveness on both health outcomes and costs of this innovative strategy. Furthermore, not much is known about the ethical considerations that are necessary for successful implementation.[28] Incorporating patients' preference is important to ensure that care is provided based on the individual patient's perspective, preferences, and needs. The findings of this study provide some suggestions for implementation from the patient perspective: these include the demand for patient education and a clear antenatal management plan, adequate participant selection for telemonitoring, daily contact (by telephone or teleconferencing) by a select group of staff for a continuum of care (as our Obstetric Telemonitoring Team) and weekly hospital visits. Regarding safety, it is recommended to work using strict protocols including equipment manuals for care providers and patients and a limit for travel time to the hospital.

This study is one of the first to report on women's perspectives on antenatal monitoring from home during high risk pregnancy. A strength of this qualitative study is the inclusion of both hospitalized women and women from the telemonitoring pilot within one center. Although there is existing knowledge of personal effects of hospitalization during pregnancy, these effects can differ due to different protocols of daily practice in different hospitals, for example visitation policies on ward, the number of private and shared rooms and other hospital facilities. By directly comparing both groups from our center, we were able to outline the different experiences and perspectives in these two groups.

Our results must be interpreted in the context of the following limitations. Selection bias

could have influenced the results, as participants of telemonitoring agreed to take part in this innovative strategy. Although findings from the focus groups were seemingly consistent, the results are not statistically powered. This study uses qualitative methods and thus provides mainly descriptive data that cannot be generalized widely. Although there are benefits of online FG's as described, the asynchronous nature of this FG method could have had its effect on the discussions between participants.

Conclusions

Telemonitoring of a high-risk pregnancy provides an innovative manner to monitor fetal and maternal condition from home. Compared to the experiences of hospital admission in high risk pregnancy, it allows women to be in a private and comforting environment during an anxious time in their lives. As future studies should further investigate the safety and cost effectiveness of this innovative strategy, women's views on the preference of telemonitoring need to be taken into consideration.

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Supplemental material 1.

Overview of questions posted in the online Facebook groups as part of the qualitative study.

Focus group questions "Hospital admission"

Question 1:
Was it clear to you (and, if applicable, your partner) why hospital admission was necessary during your pregnancy? How did you feel about the admission, at first?

Question 2:
During your admission, was the management plan regarding your complicated pregnancy clear to you? And was it possible to speak to as physician, midwife or nurse in an accessible manner?

Question 3:
Can you tell us about your thoughts about the admission; did you feel it was necessary or useful?

Question 4:
Can you tell us about the effects of our hospitalization on your partner or family at home, if applicable? How did they manage with work, school, family and your admission?

Question 5:
The longer your admission lasted, did you recognize a change in perception? For exemple, did you feel more relaxed, or bored, or more anxious?

Question 6:
During admission, how did you feel about your freedom of movement and your daily activities? Was it possible to move around, or were you confined to bed, or bed rest?

Question 7:
Can you tell us more about privacy? Were you able to find a place for you alone on ward? Did you manage to do things for yourself?

Question 8:
Can you tell something about hospital facilities, such as food, television, beds?

Question 9:
Is there something you feel you want to share with us, in ways of points of attention or negative points about hospital admission?

Question 10:
Is there something you feel you want to share with us, in ways of the positive points about hospital admission?

Focus group questions "Telemonitoring"

Question 1:
Was it clear to you (and, if applicable, your partner) why increased monitoring was necessary during your pregnancy? How did you feel about this increased surveillance, at first?

Question 2:
During your period of telemonitoring, was the management plan regarding your complicated pregnancy clear to you? And was it possible to speak to a physician, midwife or nurse in an accessible manner?

Question 3:
Can you tell us about your thoughts about the weekly outpatient visits during telemonitoring; did you feel it was necessary or useful?

Question 4:
How are your experiences with use of the devices at home? Was it easy to use, or did the devices or technique let you down sometimes?

Question 5:
How did you combine home-based telemonitoring with life at home? Did you feel like you were still 'admitted'? Or did your daily life (if applicable with your partner and other kids) just continue as normal?

Question 6:
The longer your telemonitoring period lasted, did you recognize a change in perception? For example, did you feel more relaxed, or bored, or more anxious?

Question 7:
When your experienced times of insecurity or anxiety, did you feel it would have helped if a nurse/midwife/physician would have been around, as would be the case on the hospital ward?

Question 8:
Can you tell something about facilities at home, compared to the facilities in the hospital or ward (if you have ever been admitted)?

Question 9:
Is there something you feel you want to share with us, in ways of points of attention or negative points about home-based telemonitoring?

Question 10:
Is there something you feel you want to share with us, in ways of the positive points about home-based telemonitoring?

CHAPTER 9

HOME-BASED MONITORING AND TELEMONITORING OF COMPLICATED PREGNANCIES – A NATIONWIDE SURVEY STUDY OF CURRENT PRACTICE IN THE NETHERLANDS

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ABSTRACT

Objective

To assess the current practice and attitudes concerning home-based monitoring (with daily home visits by obstetric professionals) and telemonitoring (using devices and Internet for daily self-recorded measurements) in high-risk pregnancies requiring maternal and fetal monitoring, in the Netherlands.

Methods

For this nationwide cross-sectional study, an online survey was sent to all 73 obstetric departments of hospitals in the Netherlands to be answered by one representative per hospital, dedicated to pregnancy monitoring. Primary outcome was the provision of home- and/or telemonitoring using cardiotocography between 1995 and 2018. The survey further addressed perspectives regarding the use of home- and telemonitoring, including (contra-) indications and (dis-)advantages for pregnant women and clinicians.

Results

Response rate regarding the provision of home- or telemonitoring was 100%. In 2018, 28 out of 73 centers in the Netherlands (38%) offered either home monitoring, telemonitoring or both to pregnant women with complications. Home monitoring was offered in 19 centers (26% of all hospitals), and telemonitoring in 17 centers (23%) and 8 centers offered both. Telemonitoring was first offered in 2009 and increased from 3 hospitals in 2014 (4%) to 17 in 2018 (23%).

Responses from 57 surveys of 73 invited hospitals (response rate 78%) were analyzed. Of 17 centers using telemonitoring, 59% did not investigate perinatal outcomes, safety and patient satisfaction prior to implementation. Six other telemonitoring centers were participating in an (ongoing) multicenter randomized clinical trial comparing patient safety, satisfaction and costs of telemonitoring with standard hospital admission. Home- and telemonitoring is provided for a wide range of complications such as fetal growth restriction, preeclampsia or preterm rupture of membranes. Respondents reported advantages of monitoring from home, such as reduced stress and increased rest for patients, and reduction of admission and possible reduction of costs. Addressed barriers included lack of reimbursement and possible technical issues.

Conclusion

Home monitoring is provided in 26% and telemonitoring in 23% of hospitals in the Netherlands to women with complications of pregnancy. Altogether, 38% of hospitals offer home monitoring, telemonitoring or both as an alternative for hospital admission. Future research is warranted to assess safety and reimbursement issues before widespread implementation of this increasing practice.

INTRODUCTION

Pregnancies with complications need close antenatal surveillance. While 7 to 10 antenatal consultations are recommended in uncomplicated pregnancies, complications result in recurrent outpatient visits or hospital admission.[1] These complications include, amongst others, fetal growth restriction (prevalence 3-7%), preeclampsia (prevalence 1-3%), and preterm prelabor rupture of membranes (prevalence 1-5%).[2-4] Daily monitoring with cardiotocography (CTG), blood pressure measurements and/or urine and blood analysis is recommended in international guidelines to assess maternal and fetal condition in high-risk pregnancy. [5-7] Ultimately, hospitalization is indicated in up to 11% of all pregnancies and usually extends to delivery and the postpartum period.[5-7] Antenatal admissions pose psychological stress to pregnant women because of separation from family and home, lack of activity and feelings of uncertainty.[8,9] In addition, hospital admissions are a burden on health care costs and workload, also in high income countries, already experiencing difficulties as a result of shortage of professional staff.[10]

From 1990 onwards, obstetric departments in the Netherlands are providing domiciliary care or "home monitoring" to women with high-risk pregnancies. As an alternative to clinical admission, home monitoring involves hospital-employed midwives or nurses visiting pregnant women with complications at home, on a daily basis. Medical tests, including CTG, are performed at home and the results are discussed with a supervising gynecologist (Fig 1a). Multiple randomized trials have proved that home monitoring with home visits is feasible and safe regarding perinatal outcome.[11-14] These trials demonstrated satisfactory outcomes for both mother and child but also that daily visits are time consuming and therefore expensive.

The use of digital health for remote monitoring in pregnancy care is increasingly popular, as pregnant women are frequent users of smartphones, internet and health related apps.[15] As an alternative to hospital admission or home monitoring with prenatal home visits, as described above, telemonitoring is a relatively new approach in high-risk pregnancy. After training of participants, daily measurements of blood pressure and CTG are self-recorded by the patient at home, and sent with Bluetooth or wifi to a secured digital platform. Using Internet connection, the data are integrated in the electronic patient file (Fig 1b). Patients are contacted by their clinician on a daily basis, to discuss presence of symptoms, results of the tests and future management. Multiple telemonitoring platforms for remote cardiotocography have been evaluated in prospective studies to prove their feasibility, including usability, accuracy of tracings and acceptability of patients and clinicians.[15]
In general, digital health has the potential to improve access to care, disease monitoring and patient satisfaction while reducing healthcare costs due to a reduction in visits and admissions. At this moment, only scarce clinical evidence is available for telemonitoring

using cardiotocography in complicated pregnancies to support these hypotheses regarding its effects on perinatal outcome, safety, patient preference and costs.

In the Netherlands, a number of obstetric centers currently provide either or both home-based monitoring and telemonitoring to women with high-risk pregnancies. It is unknown to which extent these strategies are used, for which reasons, or for which pregnancy complications. This information is relevant for clinicians planning to use a telemonitoring strategy in prenatal care. The aim of this national survey study is to determine the number of obstetric hospitals in the Netherlands that provide home- and telemonitoring, and to identify the current practice of out-of-hospital care in in high-risk pregnancy.

Figure 1. Definition and illustration of (A) home monitoring and (B) telemonitoring in pregnancy.

	A. Home-based monitoring	B. Telemonitoring
Definition	Daily pregnancy monitoring with the help of hospital personnel traveling to pregnant women's homes	Daily pregnancy monitoring with the help of devices used by pregnant women at home in the absence of hospital personnel
Illustration		

METHODS

We conducted a nationwide cross-sectional study using an online survey amongst obstetric care professionals. All hospitals with pregnancy and childbirth care departments in the Netherlands (n=73) were invited to participate in our survey. They were asked to appoint one of their obstetric professionals, dedicated to (remote) pregnancy monitoring, as representative of the department to answer the questions on behalf of the practice. After receiving additional information about the purpose of the study, access was provided to our online SurveyMonkey survey. The survey was sent in November 2018 followed by a maximum of three e-mail reminders. Non-respondents were contacted once more by phone to answer the principal question: Does your center currently offer home- or telemonitoring in pregnancy?

The survey was self-developed and was based on expert knowledge of home- and telemonitoring in the Netherlands. A professor of obstetrics, a perinatologist, a hospital-based midwife and 2 researchers, all with extensive experience in home-based monitoring of risk pregnancies, were involved in its development. It contained a maximum of 44 questions depending on whether home- or telemonitoring was offered. The open and multiple-choice questions addressed four domains: 1. Basic demographics of the respondent; 2. Home-monitoring; 3. Telemonitoring; 4. Advantages and disadvantages of home-and telemonitoring as perceived by the respondent (See Multimedia Appendix 1).

Total number of births per year were asked in order to compare hospitals with reference to their size. Regarding the provision of home- or telemonitoring, the year of start and, if applicable, year of discontinuation was asked. We defined our study period from 1995 to 2018. Questions regarding indications, management protocols, and (dis)advantages of the strategies, were asked to be answered with the centers' practice of year 2018 in mind. In the introduction of our survey, home monitoring was defined as: daily pregnancy monitoring with help of hospital personnel traveling to the pregnant women's home. Telemonitoring was defined as: daily pregnancy monitoring with help of devices used by the pregnant women at home in absence of hospital personnel (Figure 1).
Simple descriptive statistics were used to describe the results.
No ethical approval was required for this study because patients were not involved.

RESULTS

Current provision of home monitoring and telemonitoring in high-risk pregnancy
In 2018, 73 hospitals in the Netherlands provided pregnancy and childbirth care. The principle question (Does your center currently offer home- or telemonitoring in pregnancy?) was answered by all 73 invitees, resulting in a response rate of 100%.

In 2018, 19 out of 73 hospitals (26%) offered home monitoring with home visits by an obstetric professional (nurse or midwife) for high-risk pregnancy. A total of 17 of 73 hospitals offered telemonitoring in 2018 to high-risk pregnant women, which is equivalent to 23% nation-wide (Table 2). Eight centers reported they offered both home monitoring with home visits as well as telemonitoring to their patients.

Table 2 The number of hospitals offering home monitoring and telemonitoring in risk pregnancy, in 2018, in relation to the number of births per hospital per year.

Number births / hospital / year	**Number of hospitals**	**Home monitoring,** n (% within same category)	**Telemonitoring** n (% within same category)
0-1000	15	0	1 (7%)
1001-2000	35	9 (26%)	8 (23%)
2001-3000	21	9 (43%)	6 (29%)
3000+	2	1 (50%)	2 (100%)
Total	73	19 (26%)	17 (23%)

In obstetric departments with <1000 births/year, home monitoring and telemonitoring is limited to 0 and 1 center, respectively. As for different types of hospitals, eight of nine Dutch tertiary care hospitals with NICU facility currently work with either home- or telemonitoring (or both) in risk pregnancy management. Geographic distribution of hospitals with home monitoring (HM) and telemonitoring (TM) is displayed of all 12 provinces of the Netherlands in Figure 2.

For the studied period of 1995-2018, the trend line in Figure 3 shows that home monitoring in pregnancy has been offered since the mid 1990s. Most of these centers kept offering daily home visits over a longer period of time, with a peak in 2015. After the introduction of pregnancy telemonitoring in 2009, the trend line of telemonitoring shows a steep increase in use from 2014 onwards: from 3 centers in 2014 (4% of hospitals in the Netherlands) to 17 centers in 2018 (23%). This increasing number is accompanied by a slight drop in home monitoring provision.

Figure 2. Geographic distribution in twelve provinces of the Netherlands:
HM: (hospitals with home monitoring) / (all hospitals in this province).
TM: (hospitals with telemonitoring) / (all hospitals in this province).
Total number of hospitals = 73.

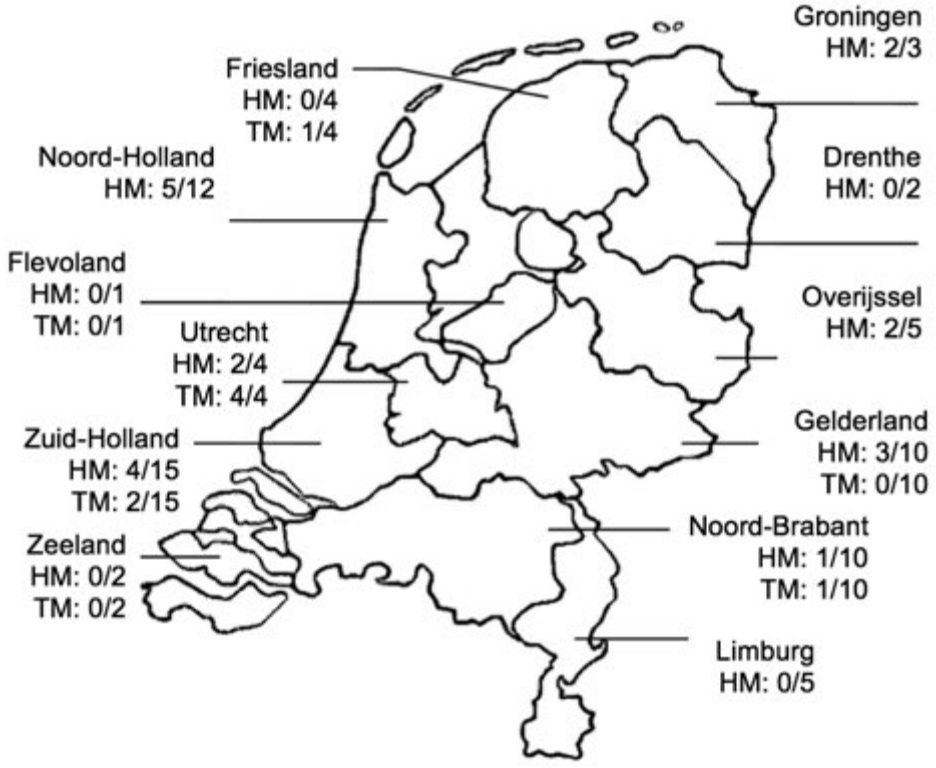
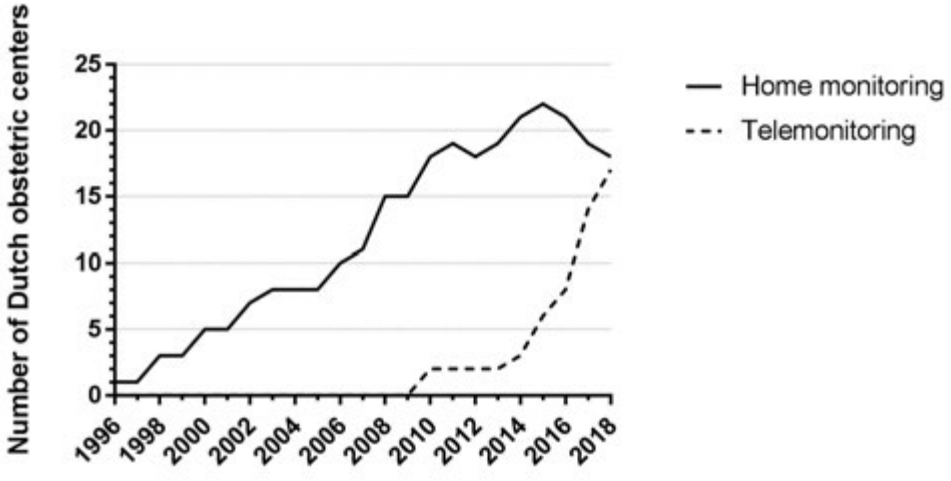


Figure 3 Trend graph of obstetric departments offering home- and telemonitoring in high risk pregnancy in the Netherlands.



Survey results

Out of 73 invitations, 57 hospitals participated in the online survey (response rate 78%). Of these 57 respondents, 26 (45%) worked in a teaching hospital, 22 (39%) in a non-teaching hospital and 9 (16%) in an tertiary care hospital with neonatal intensive care unit. Of the responding 57 hospitals, 8 (14%) had 0-1000 births/year, 29 (51%) 1001-2000 births/year, 18 (32%) 2001-3000 births/year and 2 (3%) over 3000.

Declining trend of home monitoring

Six units (11%) did offer home monitoring in the years between 1995-2018 but stopped performing pregnancy monitoring with home visits. Median number of years of home monitoring provision was 7.5 years (range 2-18 years). Several reasons for their discontinuation were given, such as: small number of possible candidates (3/6), problems with staff capacity (3/6), problems with the financial capacity to continue home monitoring (2/6) and switching over to telemonitoring without home visits (2/6).

Eight of 19 hospitals with home monitoring (42%) considered switching to telemonitoring, stating that it seems to contribute to more patient satisfaction and it does not require hospital staff to visit patients at home. Three hospitals providing home monitoring did not consider to change to telemonitoring because they are satisfied with their current home monitoring strategy. With telemonitoring, they stated, there is no daily direct clinical assessment of the patient by a nurse/midwife and no possibility to monitor twin pregnancies.

Evaluation of use

In 12/19 hospitals with home monitoring (63%), implementation of home monitoring was not preceded by a center-specific evaluation phase of home-monitoring. However, home monitoring in these centers mainly started after the publication of two Dutch trials concluding its patient safety and positive effects on satisfaction of care.(7,8)

As for telemonitoring, 6 of 17 centers (35%) were participating in a multicenter randomized controlled trial comparing clinical hospital admission with telemonitoring in pregnancies requiring daily fetal monitoring. Aim of this trial is to compare patient safety, user satisfaction and cost-effectiveness; its protocol can be found elsewhere.16 The remaining ten centers (59%) reported they did not participate in nor started evaluation of use of this novel strategy with daily self-measurements prior to implementation in complicated pregnancies in their centers.

Indications and management in home-based pregnancy monitoring

Responding centers with either home- or telemonitoring reported similar lists of pregnancy complications, which they considered eligible for daily monitoring outside their hospital (Table 4). Both fetal growth restriction and preterm rupture of membranes are considered eligible for home- as well as telemonitoring in every center.

Table 4. Indications for home monitoring (n = 19 hospitals) and telemonitoring (n= 17 hospitals)

Indications	Home monitoring centers n (%)	Telemonitoring centers n (%)
Fetal growth restriction	19 (100%)	17 (100%)
Preterm premature rupture of membranes	19 (100%)	17 (100%)
Prolonged prelabor rupture of membranes at term	5 (26%)	2 (12%)
Isolated oligohydramnios	10 (53%)	4 (24%)
Reduced fetal movements	15 (79%)	15 (88%)
Fetal anomalies requiring fetal monitoring	9 (47%)	3 (18%)
(Adverse) Obstetric patient history^	16 (84%)	15 (88%)
Hypertensive disorders of pregnancy	15 (79%)	10 (59%)
Cholestasis of pregnancy	14 (74%)	5 (29%)
Other maternal co-morbidity*	11 (58%)	4 (24%)
Social or psychological distress	11 (58%)	5 (29%)

^ e.g. intrauterine fetal death in a previous pregnancy

** e.g. (gestational) diabetes mellitus, kidney disease, cardiac disease requiring maternal monitoring*

All 18 home monitoring centers reported that at home, midwives or nurses measure patients' blood pressure and perform a CTG during their visits. In 15/18 centers (83%), it is possible to monitor fetal condition of both singleton and twin pregnancies using CTG. Additionally, urine analysis (72%), venous blood sampling (67%) and medication administration (22%) can be performed by the professional at home. This is in contrast to telemonitoring centers where no other tests besides blood pressure and CTG are performed by patients themselves, at home.

Hospitals with either home- or telemonitoring also reported on patient-specific contra-indications for monitoring from home. These contra-indications were: impossibility to keep to agreements or difficulty to understand the system (94%), long home-to-hospital distance (89%), present antepartum hemorrhage (72%) and vulnerable home situation or social issues of the patient (50%). Other mentioned general contra-indications were: gestational age < 25 weeks, and PPROM without engaged fetal head or breech. To ensure the safety of the patients to minimize the travel time if complications occur, respondents made clear that patients must reside within 30 to 35 km away from their hospital.

Reported (dis)advantages of home – and telemonitoring

The most frequently addressed advantages of home-and telemonitoring for the patients, as perceived by the respondents, include more patient-comfort and less emotional burden of hospitalization for the patient, as they continue with daily (family) life and activities as much as possible. Other frequently mentioned advantages are summarized in Textbox 1.

Possible disadvantages of home-monitoring and telemonitoring for the patient include the possibility of a delay in providing help in case of an emergency or acute problem, because the patient is not physically present in the hospital. Technical issues and insecurity regarding the devices are also mentioned (Textbox 1).

Text ox 1: Advantages and disadvantages of home- and telemonitoring for patients, as addressed by 57 respondents.

Advantages	n (%)
Improved patient comfort	40 (70)
Reduced (emotional) burden of admission	35 (61)
Reduced stress/more rest	25 (44)
Better patient autonomy	21 (37)
Higher patient satisfaction	8 (14)
Higher patient safety	7 (12)
Reduced over-medicalization during pregnancy	2 (4)
Disadvantages	n (%)
Possible delay in providing help during emergencies or acute problems	38 (67)
No direct communication with the consulting gynecologist	18 (31)
Patients' inability to conduct CTGa at home	13 (23)
Technical issues	17 (30)
Inability to follow instructions	12 (21)

Respondents reported a number of perceived benefits of home- and telemonitoring for the healthcare provider, the most important being the reduction of admissions, which in turn may reduce health care costs (45 of all 57 respondents, 79%) and less burden on the hospital personnel (46%). Most mentioned disadvantages of home- and telemonitoring for clinicians are: costs and reimbursement (66%), impossibility of direct patient assessment (32%) and specific for the home monitoring: lack of sufficient obstetric personnel to make home visits (38%).

Number of high-risk pregnant women managed from home

In all 19 home monitoring centers combined, respondents reported a minimum of 745 to a maximum of 1140 patients with a singleton pregnancy were monitored with home visits in 2018 in the Netherlands.

The telemonitoring centers responded that, in their 17 centers combined, a minimum of 400 to a maximum of 725 patients with a singleton pregnancy were monitored with remote monitoring devices in 2018 in the Netherlands.

Altogether, in 2018 in the Netherlands, 1145 to 1865 women with a complicated pregnancy were managed at home with home-monitoring and telemonitoring, as an alternative to hospital admission.

DISCUSSION

Main findings

Our survey results show the current practice in the Netherlands regarding the use of home monitoring and telemonitoring in high-risk pregnancy. In 1995 pregnancy monitoring with daily home visits was available in only a few obstetric hospitals, yet currently it is used by 26% of all hospitals in the Netherlands. The last five years, a steep increase in provision of telemonitoring is observed, as off 2018 it is used in 17 centers, or 23%, of all obstetric departments. Furthermore, almost half of the hospitals with home monitoring considered switching to telemonitoring using self-measurement of fetal and maternal parameters. Of 17 telemonitoring centers, 10 centers did not evaluate use of this digital health strategy with daily self-measurements prior to implementation in their centers. Six centers were currently participating in an ongoing trial to compare traditional hospital admission and telemonitoring for patient safety, satisfaction and costs.

In 2018, 1145 to 1865 pregnant women were monitored from home with home visits or telemonitoring in pregnancy after diagnosis of complication(s).

Strengths and limitations

Our study is a nationwide survey with high response rate and includes both secondary- and tertiary referral centers, teaching- and nonteaching centers and wide range of small to large units according to annual birth numbers. Responses of the survey depended on voluntary participation of invited hospitals, which could have led to selection bias. Furthermore, the collected data were self-reported and hence subjective. Part of the results on the impact of remote monitoring was based on estimations by respondents, and this may limit the validity of the conclusions. The evaluation of characteristics of pregnant women, relevant clinical outcomes (including safety) and user experiences are critical for future health care improving with use of mobile monitoring. However, this study was not set up to evaluate these outcomes, which might be considered a current limitation of this study.

Interpretation

The level of application of digital health in prenatal care is evident, with the focus on pregnancy telemonitoring as one of the most promising additions to new care models.[9,15,17] Respondents of our survey identified important (perceived) advantages of telemonitoring: more patient friendly care in respond to their needs, increased patient satisfaction and autonomy and reduced over-medicalisation. These results are in line with previous research of patient experiences with digital health.[15,18,19] Furthermore, obstetric care professionals also underline the importance of digital health in pregnancy care in previous studies. A survey study conducted in Belgium concluded that 28/35 (80%) midwives and 6/9 (67%) obstetricians, who worked with remote blood pressure monitoring in pregnancy, felt that digital technologies are an important component in prenatal monitoring.[20]

Moreover, a survey amongst 89 German physicians concluded that nearly 70% considered apps for pregnancy monitoring reasonable.[21] Other reported advantages in favor of telemonitoring are the reduction of admissions and burden on hospital personnel.[18,19] Staff shortages are also demanding for a shift from hospital to home-based care.
In the Netherlands, approximately 170,000 children are delivered per year, both from uncomplicated as well as complicated pregnancies. We estimated earlier that 11% of pregnant women need antenatal hospital admission because of complications, which equals to 18,700 women yearly. With use of our respondents' results, we calculated that 1,145 to 1,865 pregnant women were monitored from home in 2018. This number roughly equals 6-10% of antenatal hospital admissions that were replaced by home- and/or telemonitoring in 2018. Although exact numbers of length of hospitalization during high-risk pregnancy are lacking, we can use these numbers to estimate the possible impact of home- and telemonitoring on admission in pregnancy. If home- or telemonitoring services in pregnancy would be used for approximately 5 days/nights per pregnant women, this would equal a reduction of 5725 to 9325 admission days otherwise spent in the hospital on ward.

The number of studies on the implementation of telemonitoring using patient-recorded daily CTG is limited. Despite this limited knowledge of the effects of pregnancy telemonitoring on perinatal outcomes, patient experiences and cost-effectiveness, this study shows that its use is increasingly popular in the Netherlands. Although not mentioned by our respondents, legal concerns, such as third party control and use of data, can be a limitation in widespread use of digital health. In the Netherlands, external companies providing the devices, software and storage of patient data of telemonitoring must commit to certain certificates for data security. Evidence from clinical trials and health technology assessments will help to better estimate the exact budgetary impact, from several different (i.e. societal, insurance, hospital) perspectives. The costs involved in development, use and maintenance of the devices, as well as the way in which they are imbedded in the current practice, are also needed to calculate the added value of pregnancy telemonitoring. Our survey respondents report challenges with reimbursement, since there is no coverage for pregnancy telemonitoring in the Netherlands. Financial issues are also the main reason given by our respondents without home- or telemonitoring, especially the smaller obstetric units. Insurance companies are well known to only cover well-researched digital health interventions with according economic evaluation.[22,23] To compare daily telemonitoring at home versus traditional hospital care for complicated pregnancies, a multi-center randomized controlled trial is currently recruiting in 6 Dutch hospitals: the HOTEL trial (HOspital admission versus TELemonitoring in high risk pregnancy).[16] This trial aims to compare both strategies with regards to perinatal outcome, patient satisfaction and cost-effectiveness.

Recommendations for research and practice

By this survey we provide information about the current practice and trends in the Netherlands regarding home- and telemonitoring in perinatal care. More detailed information on barriers and facilitators from both patients and health care providers may help further development of innovative strategies in perinatal care. However, evidence on medical outcomes and patient safety of telemonitoring is still lacking and is required before implementation of this innovation in the target group. We must expand our knowledge of these forms of care in order to move forward with digital health innovations. Consensus on the implementation and research agenda can pave the road to widespread use of digital health services. Trial results, combined with stakeholders' views of digital health, are needed for the development of reimbursement systems of innovative methods for remote monitoring in pregnancy.

Conclusion

In 2018 in the Netherlands, 26% of the hospitals offered home-monitoring and 23% offered telemonitoring to their patients with pregnancy complications. With these increasingly popular forms of home-based care, an increasing number of pregnant women in need of daily monitoring is staying at home, as an alternative to hospital admission. Additionally, respondents of the survey addressed multiple possible advantages and disadvantages of home- and telemonitoring in pregnancy. These results can contribute to future evaluation of digital innovations in pregnancy care, as further research on safety, experience and cost-effectiveness is warranted before widespread implementation.

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Multimedia Appendix 1: All questions of the survey

For all hospitals:

1. Your hospital lies in which province of the Netherlands?
   Options: Groningen, Friesland, Drenthe, Overijssel, Flevoland, Gelderland, Utrecht, Noord-Holland, Zuid-Holland, Zeeland, Noord-Brabant, Limburg
2. Your hospital is a
   - Secondary obstetric care center
   - Tertiary obstetric care center (With NICU facility)
3. Is your hospital a teaching hospital?
   Options: yes, no
4. What is the estimated number of deliveries per year in your hospital
   Options: 0-1000, 1001-2000, 2001-3000, 3001 or more
5. What is your function?
   Options: gynaecologist, midwife, nurse, other
6. Does your hospital currently provide home monitoring
   Options: yes; no, but we did in the past; no
7. Does your hospital currently provide tele-monitoring
   Options: yes; no, but we did in the past; no

For hospitals with current home monitoring:

8. Since what year does your hospital provide home monitoring
   Open question
9. Does your hospital work with a local guideline regarding pregnancy home monitoring
   Options: yes, no
10. Did your hospital conduct a local evaluation of home monitoring regarding patient safety before implementation?
    Options: yes, no,
11. Did your hospital conduct a local evaluation of home monitoring regarding patient experiences before implementation?
    Options: yes, no
12. What medical checks are performed at home by hospital personnel? Multiple options possible
    Options: physical examination, CTG, blood pressure, temperature, urine sampling, draw blood, give medication (for example corticosteroids), other…
13. What groups of high risk pregnancy are eligible for home monitoring in your hospital? Multiple options are possible.
    Options: FGR, PPROM, preeclampsia, decreased fetal movements, (gestational) hypertension, cholestasis of pregnancy, fetal anomalies requiring surveillance, (gestational) diabetes mellitus, prolonged prelabor rupture of membranes at term, isolated oligohydramnios, (adverse) obstetric patient history, social or psychological stress, other maternal co-morbidity, other..
14. Do you monitor multiple pregnancies using home monitoring
    Options; yes, no
15. What contra-indications of home monitoring do you use? Multiple options possible
    Options: antepartum haemorrhage, long home-to-hospital distance, non-compliance to agreements, other
16. What is the maximum distance for home monitoring eligibility?
    Open question
17. What is the minimum gestational age for home monitoring eligibility?
    Open question
18. What is the estimated number of singleton pregnancies that are monitored with home monitoring per year in your hospital?
    Options: 0-5, 5-10, 10-25, 25-50, 50-75, 75-100, >100
19. What is the estimated number of multiple pregnancies that are monitored with home monitoring per year in your hospital?

Options: 0-5, 5-10, 10-25, 25-50, 50-75, 75-100, >100

20. What is the estimated number of days that each high-risk pregnant woman is monitored at home?
Options: 0-5, 5-10, 10-15, >15

For hospitals that discontinued home monitoring:

21. From what year to what year did your hospital provide home monitoring?
Open question

22. Why did your hospital stop providing home monitoring? Multiple options possible.
Options: small number of possible candidates; patients were not interested; obstetric professionals were not interested; not enough staff capacity for home visits; problems with financial capacity to continue home visits; we switched to TELEmonitoring without home visits.

23. Is your hospital planning to re-start with home monitoring?
Options Yes, why; no, why not

For hospitals without current home monitoring:

24. Why is your hospital currently not providing home monitoring?
Options: Options: small number of possible candidates; patients were not interested; obstetric professionals were not interested; not enough staff capacity for home visits; problems with financial capacity to continue home visits; we provide TELEmonitoring without home visits; other..

25. Is your hospital planning to start providing home monitoring?
Options Yes, why; no, why not(...)

For hospitals with current telemonitoring:

26. Since what your did your hospital stat telemonitoring:
Open question

27. What medical check are performed by the pregnant woman herself at home? Multiple options possible.
Options: CTG, blood pressure, temperature, urine analysis, other..

28. Does your hospital work with a local guideline regarding pregnancy telemonitoring
Options: yes, no

29. Did your hospital conduct a local evaluation of telemonitoring regarding patient safety before implementation?
Options: yes, no,

30. Did your hospital conduct a local evaluation of telemonitoring regarding patient experiences before implementation?
Options: yes, no

31. What groups of high risk pregnancy are eligible for telemonitoring in your hospital? Multiple options are possible.
Options: FGR, PPROM, preeclampsia, decreased fetal movements, (gestational) hypertension, cholestasis of pregnancy, fetal anomalies requiring surveillance, (gestational) diabetes mellitus, prolonged prelabor rupture of membranes at term, isolated oligohydramnios, (adverse) obstetric patient history, social or psychological stress, other maternal co-morbidity, other..

32. Do you monitor multiple pregnancies using telemonitoring
Options; yes, no

33. What contra-indications of telemonitoring do you use? Multiple options possible
Options: antepartum haemorrhage, long home-to-hospital distance, non-compliance to agreements, other

34. What is the maximum distance for telemonitoring eligibility?
Open question

35. What is the minimum gestational age for home monitoring eligibility?
Open question

36. What is the estimated number of singleton pregnancies that are monitored with telemonitoring per year in your hospital?
    Options: 0-5, 5-10, 10-25, 25-50, 50-75, 75-100, >100
37. What is the estimated number of multiple pregnancies that are monitored with telemonitoring per year in your hospital?
    Options: 0-5, 5-10, 10-25, 25-50, 50-75, 75-100, >100
38. What is the estimated number of days that each high-risk pregnant woman is monitored using telemonitoring at home?
    Options: 0-5, 5-10, 10-15, >15

For hospitals without current telemonitoring:

39. Why is your hospital currently not providing telemonitoring?
    Options: Options: small number of possible candidates; patients were not interested; obstetric professionals were not interested; not enough staff capacity for home visits; problems with financial capacity to continue home visits; we provide home monitoring with home visits; other..
40. Is your hospital planning to start providing telemonitoring?
    Options Yes, why; no, why not

For all hospitals:

41. From the viewpoint of the obstetric care professional: can you mention 3 advantages of monitoring risk pregnancies from home?
    Open question
42. From the viewpoint of the obstetric care professional: can you mention 3 disadvantages of monitoring risk pregnancies from home?
43. From the viewpoint of the pregnant women: can you mention 3 advantages of monitoring risk pregnancies from home?
44. From the viewpoint of the pregnant women: can you mention 3 disadvantages of monitoring risk pregnancies from home?

9

CHAPTER 10

HOSPITAL CARE VERSUS TELEMONITORING IN HIGH-RISK PREGNANCY (HOTEL): STUDY PROTOCOL FOR A MULTICENTRE NON-INFERIORITY RANDOMISED CONTROLLED TRIAL

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ABSTRACT

Introduction

Pregnant women faced with complications of pregnancy often require long-term hospital admission for maternal and/or fetal monitoring. Antenatal admissions cause a burden to patients as well as hospital resources and costs. A telemonitoring platform connected to wireless cardiotocography (CTG) and automated blood pressure devices can be used for telemonitoring in pregnancy. Home telemonitoring might improve autonomy and reduce admissions and thus costs. The aim of this study is to compare the effects on patient safety, satisfaction and cost-effectiveness of hospital care versus telemonitoring (HOTEL) as an obstetric care strategy in high-risk pregnancies requiring daily monitoring.

Methods and analysis

The HOTEL trial is an ongoing multicentre randomized controlled clinical trial with a non-inferiority design. Eligible pregnant women are >26+0 weeks of singleton gestation requiring monitoring because of preeclampsia (hypertension with proteinuria), fetal growth restriction, preterm rupture of membranes without contractions, recurrent reduced fetal movements, or an intrauterine fetal death in a previous pregnancy.

Randomisation takes place between traditional hospitalization versus telemonitoring until delivery. During telemonitoring pregnant women at home will use the Sense4Baby CTG device and Microlife blood pressure monitor and they will have daily telephone calls with an obstetric health care professional as well as weekly visits to the hospital.

Primary outcome is a composite of adverse perinatal outcome, defined as perinatal mortality, 5-minute Apgar < 7 or arterial cord blood pH < 7.05, maternal morbidity (eclampsia, HELLP syndrome, thromboembolic event), neonatal intensive care admission and caesarean section rate. Patient satisfaction and preference of care will be assessed using validated questionnaires. We will perform an economic analysis. Outcomes will be analysed according to the intention to treat principle.

Ethics and dissemination

The study protocol was approved by the Ethics Committee of the Utrecht University Medical Center and the boards of all six participating centres. Trial results will be submitted to peer-reviewed journals.

Trial registration NTR6076, (September 2016)

INTRODUCTION

For pregnant women diagnosed with complications, increased monitoring and observation of maternal and fetal parameters is recommended.[1] The aim of daily monitoring in high-risk pregnancies is to assess fetal and maternal condition using tests such as blood pressure (BP), urinary and blood analysis and cardiotocography (CTG). This increased surveillance essentially leads to antenatal hospitalisation in up to 11% of pregnancies, mostly for preterm rupture of membranes (PROM), fetal growth restriction (FGR), (gestational) diabetes mellitus, imminent preterm birth, fetal anomalies, and hypertensive disorders including preeclampsia (PE).[2,3,4] These admissions, often until delivery, result in dissatisfaction with the in-hospital stay, family burden and significant costs.[5,6]

Recent technological advancements in health care (eHealth) have resulted in remote monitoring platforms, mobile device-supported care, telemedicine and teleconsultation.[7] eHealth has the potential to increase patient engagement and empowerment and create better access to health care while reducing the necessity for hospital visits or admittance.[8] Pregnant women are frequent users of smartphones and internet, and therefore already equipped with the hardware to take self-measurements at home and the mind-set to communicate these digitally with their prenatal care professional.[9] Telemonitoring of pregnancy is perceived to be one of the most promising answers to the possibilities of e-health in antenatal care.

Using a validated automated blood pressure monitoring device (Microlife WatchBP) and a wireless, portable CTG system (Sense4Baby), a telemonitoring strategy could replace hospital admission that require these types of monitoring.[10,11] Measurements, self-recorded by the pregnant women at home, are saved on the included tablet in a personal profile. Using a secured Internet portal, the data are integrated in the electronic patient record system enabling access for health care professionals. A pilot study (n=76) using the Sense4Baby system was performed in UMC Utrecht to examine the accuracy of the tracings, the system's usability and participants' experiences and acceptability. Feedback and experiences from participants were positive about the used technology and no clinical relevant adverse events occurred (unpublished data, see also Patient involvement under Methods).

Currently, no clinical trials have evaluated this novel strategy with telemonitoring of self-recorded data in high-risk pregnancy before. While the patient at home will take care of measurements of CTG and blood pressure, a considerable amount of time could be saved on hospital ward or outpatient clinic for health care providers. Telemonitoring might therefore reduce costs and might offer a more acceptable form of pregnancy care.[12] However, risks of unevaluated implementation of digital innovations include usability problems, issues regarding safety and reimbursement, and adverse effects, resulting in disappointing

adoption by the end-users. Therefore, patient safety and effectiveness of telemonitoring compared to antenatal admission have yet to be examined in a prospective trial.

In the HOTEL trial, a multicentre randomised controlled trial, we aim to compare hospital care to telemonitoring in high-risk pregnancy requiring daily monitoring. We will evaluate patient safety and clinical effectiveness as well as patient satisfaction and cost effectiveness of both strategies.

METHODS

Design and setting

This ongoing multicentre randomised controlled trial will be performed in 6 Dutch perinatal care units, including 2 university hospitals. The study will be open label. The trial protocol was registered in September 2016 (NTR6076) and first inclusion took place in December 2016.

Patient and public involvement

Prior to the start of the trial, pregnant women were involved in study set up. A pilot study was performed to check feasibility and acceptance of telemonitoring in pregnancy (see under Introduction). In focus groups, women with either antenatal admission or participation in the telemonitoring pilot joined our focus group studies (total n = 22) to report on satisfaction of antenatal care.

Hospitalized patients recalled anxiety, boredom and concerns about privacy on ward. Their family life was disturbed because of frequent travelling of partners and worries over their other child(s). The patients in the home telemonitoring group reported that use of the monitoring devices was uncomplicated after instruction. They reported relief about sleeping at home, better food, seeing partners and first child(s) more often and good feeling of security with at home monitoring and weekly face-to-face visits. With use of these focus group interviews, the telemonitoring strategy and study communications were improved and we developed the questionnaire that is used at the end of the study period.

Eligibility criteria

Definitions of the inclusion criteria are fully described in Table 1. Eligible women must be ≥ 18 years old with a singleton pregnancy ≥ 26+0 weeks gestational age requiring hospital admittance for maternal or fetal surveillance for one (or multiple) of the following reasons: (1) preeclampsia; (2) preterm prelabour rupture of membranes (PPROM) without contractions; (3) fetal growth restriction (FGR); (4) recurrent reduced fetal movements; (5) fetal anomaly requiring daily monitoring (e.g. fetal gastroschisis); (6) intrauterine fetal death in previous pregnancy.

Exclusion criteria for participation in the study are (1) pregnancy complications requiring

intravenous therapeutics or expected obstetric intervention within 48 hours; (2) current blood pressure >160/110 mmHg; (3) active antepartum haemorrhage or signs of placental abruption; (4) CTG registration with abnormalities indicating fetal distress or hypoxia; (5) place of residence > 30 minutes travel distance from a hospital; (6) multiple pregnancy; (7) insufficient knowledge of Dutch or English language or impossibility to understand training or instructions of telemonitoring devices.

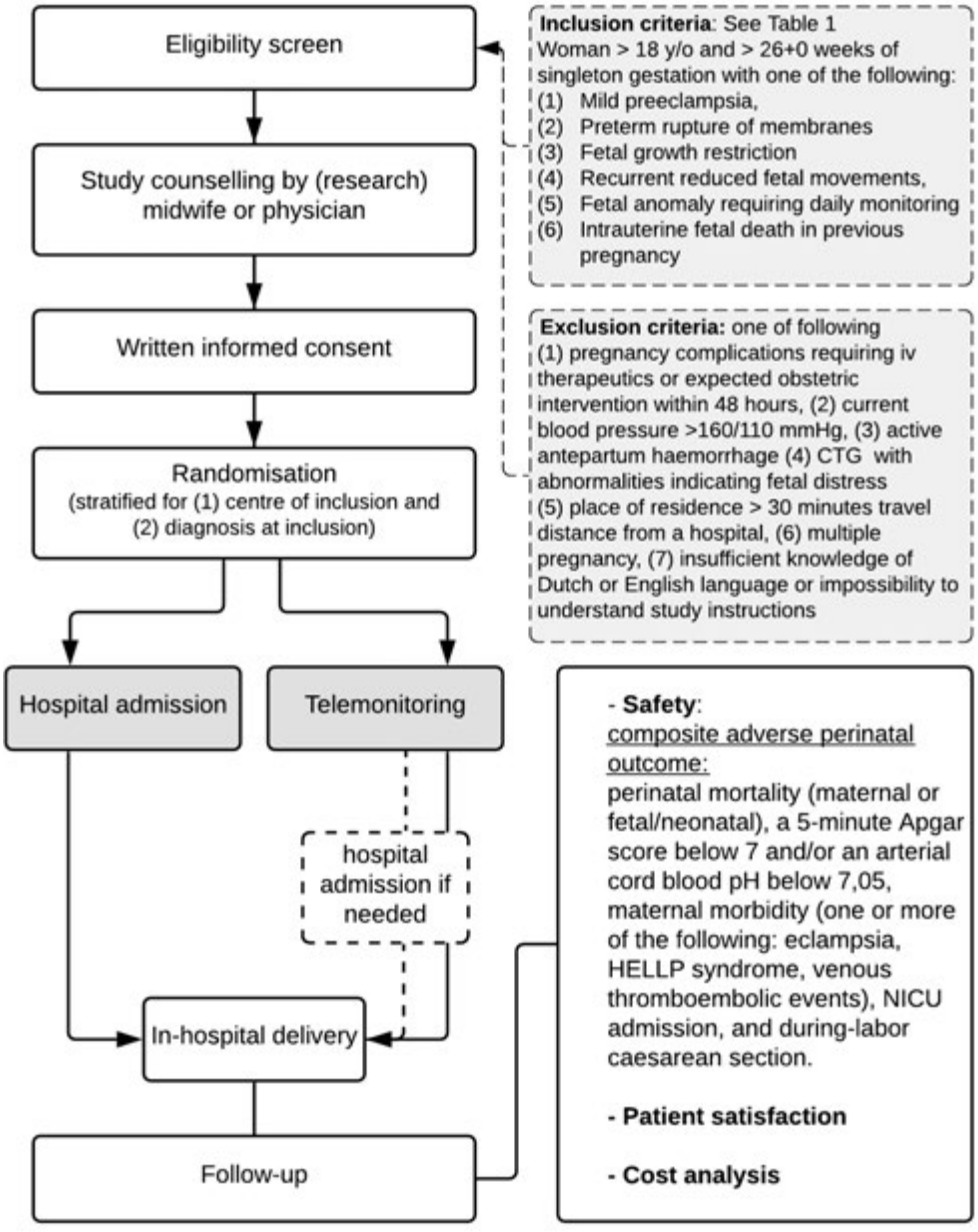
Recruitment and randomisation

Eligible women will be approached and informed by obstetric care professionals i.e. physicians, (research) midwives or research nurses. Following counselling and sufficient time for questions, written informed consent is obtained and participants will be randomly allocated in a 50:50 ratio to either hospital admission or telemonitoring. Randomisation will be performed through a secured web-based domain (Research Online, Julius Research Support, UMC Utrecht) and will be stratified for 6 diagnoses for inclusion and 6 centres of inclusion. Block randomisation with variable block sizes is used. Cross over of trial arm is not permitted and will be considered a protocol violation. An overview of the study procedures is shown in Figure 1.

Table 1 Additional information on inclusion criteria.

	Inclusion criteria	Additional definitions or criteria (other than exclusion criteria)
1	Preeclampsia	Defined as: - hypertension (diastolic blood pressure > 90 mmHg and/or systolic blood pressure > 140 mmHg with proteinuria following ISSHP criteria at the time of study design (FGR is defined below) [13] - no restriction on use of oral antihypertensive medication
2	Preterm rupture of membranes	- No present contractions - cephalic or breech position, with engaged fetal head or breech
3	Fetal growth restriction	Defined as: - fetal abdominal circumference (fAC) or estimated fetal weight (EFW) <10th percentile and abnormal Doppler sonography assessment defined as pulsatility index (PI) of umbilical artery >p95 and/ or absence or reversed end diastolic flow velocity flow of umbilical artery - fAC or EFW <p3 with or without abnormal umbilical artery Doppler flow
4	Recurrent reduced fetal movements	
5	Fetal anomaly requiring daily monitoring	
6	Intrauterine fetal death in previous pregnancy	

Figure 1 : Flowchart of study procedures



After randomisation for telemonitoring, the participant will be trained in using the medical devices involved in the system (Sense4Baby CTG system and the Microlife Watch BP, both CE marked). The training will be conducted using standardized instructions of use. The instructions include a contact sheet with telephone numbers for technical or health related questions, accessible 24/7. Each participant will receive an individual treatment plan according to national and/or local guidelines, including fetal CTG monitoring and blood pressure measurement, both once daily. Participants at home are contacted by phone every day by the telemonitoring team, to discuss present symptoms or questions regarding the pregnancy. Possible protocolled steps in the management, after the uploaded test results are checked, are: 1) expectant management, 2) same-day clinical assessment (e.g. in case of CTG abnormalities, rise in BP or symptoms) or 3) if necessary clinical admission.
The participant will visit the outpatient clinic at least once a week for real-time contact and when needed ultrasound assessment, blood or urinary analysis. Should hospital admission be necessary in case of change in clinical presentation or deterioration (e.g. non-reassuring CTG, hypertension, contractions, antepartum haemorrhage, signs of infection, maternal distress or technical difficulties), the patient will be monitored in the hospital as per local protocol and all data of interest during the admission will be collected. In the case this same participant can be discharged from ward again (e.g. after treatment optimisation for hypertension), she may go home with telemonitoring - as per randomisation- until delivery. All consultations in the outpatient department and possible ward admissions during pregnancy will be recorded for the study.

Control group: hospital admission

Pregnant women allocated to hospital admittance will receive standard obstetric care according to national and local guidelines and current state of the art, including daily fetal monitoring and blood pressure measurements. All participating centres committed to following guidelines for different diagnoses and management as set by the Dutch Society of Obstetrics and Gynecology. A typical regime on ward includes vital parameter check (blood pressure, temperature on indication) by obstetric nurses, daily cardiotocography and daily rotations for iby a resident in obstetrics and gynaecology, supervised by an obstetrician, for interpretation of results and further management. Blood and/or urine sampling and fetal ultrasound will be performed when indicated and according to local protocol. In case the necessity of hospital admission is no longer present, the patient may be discharged and if necessary admitted to ward again, as per randomisation, not allowing cross-over to telemonitoring.

Outcome measures

The primary outcome is maternal and fetal/neonatal safety during perinatal care from study inclusion onwards by recording incidence of perinatal mortality and maternal and neonatal morbidity. The composite of adverse perinatal outcome is defined as: perinatal mortality

(maternal or fetal or neonatal), a 5-minute Apgar score below 7 and/or an arterial pH below 7,05, maternal morbidity (one or more of the following: eclampsia, HELLP syndrome, thromboembolic events), NICU admission of the new-born and caesarean section rate. The components of the composite outcome are both chosen for either (or both) the possibility to be affected by the new intervention as well as the severity as a stand-alone adverse outcome. All components will be reported separately as a secondary outcome for interpretation of study results.
Secondary outcome will consist of patient satisfaction, quality of life and cost effectiveness. The satisfaction, experience and quality of life of every participating pregnant woman will be surveyed with help of the EuroQol 5D (EQ-5D), State Trait Anxiety Inventory (STAI) and Edinburgh Postnatal Depression Score (EPDS) questionnaires.[14,15,16] Surveys are sent by e-mail at study start, and 1, 3, 5 weeks after randomisation and 4 weeks after delivery. With the help of focus group discussion (see under Patient involvement), we created a questionnaire which will be filled out 4 weeks after delivery.

The cost effectiveness and budget impact analyses (CEA and BIA) will be assessed from different perspectives, i.e. hospitals, health insurance companies and from the societal perspective. The budget impact analysis will follow ISPOR guidelines for budget impact analyses to calculate the differences in budgetary impact of telemonitoring and hospital admittance in high-risk pregnancies. For the CEA and the BIA, we will record duration of telemonitoring and duration of admittance (number of days), number of consultations and health care provider involved, number and length of CTG registration, number of maternal blood analyses and ultrasound assessments, emergency transport to the hospital and emergency caesarean sections. Besides this maternal use of health services, all health service use of the newborn during the follow-up period (until discharge to home) will be recorded.

Sample size

Before the start of the trial, we formed an expert panel, consisting of gynaecologists, and paediatricians, methodologists, and statisticians to conceive the design, content, and execution of the trial. The sample size calculation is based on the assumption that the composite of adverse perinatal outcome will be equal in the telemonitoring and the hospital admittance patient groups: a non-inferiority trial. To estimate this risk for each individual component of adverse perinatal outcome in our inclusion criteria, we made use of the results of three large Dutch randomised controlled trials for patients with PPROM, FGR and preeclampsia.[17,18,19] No data on perinatal outcome of telemonitoring in high risk pregnancy are available to use in our sample size calculation. The incidence of this composite primary outcome in the high-risk pregnancy group is assumed to be 20% in either group. The panel made a reasoned choice about the acceptable difference in adverse perinatal outcome and feasibility of the trial, since this is the first ongoing trial of telemonitoring in complicated pregnancies. As a result, the non-inferiority margin (Δ) was defined as a 10% absolute

increase or less in the telemonitoring group. With a one sided α of 0.05, the study will achieve a power (β) of more than 0.80 if 200 women will be included in each trial arm (400 women in total).
The sample size was calculated for non-inferiority testing with the one-sided Score test (Farrington & Manning) using PASS software.

Data handling, analysis and result reporting
At study entry, baseline data like patient demographics, medical and obstetric history and current pregnancy details are collected. At delivery relevant data will be collected for the assessment of perinatal outcomes such as gestational age at birth, birth weight, condition at birth (Apgar scores, umbilical cord blood gas analysis), neonatal admission (type of ward and number of days). Neonatal mortality and morbidity will be specified. For the mother, data will be collected on treatment for pain relief, mode of delivery and adverse outcomes (eclampsia, thromboembolic events and HELLP syndrome). Standardized online case record forms developed by Julius Centre for Research Support (UMC Utrecht) are used, including source data verification options. Missing data will be handled according to the complete-case analysis principle, based on the availability of the components needed to determine the primary endpoint.

Primary outcome
Data analyses will primarily be carried out according to the intention-to-treat principle, i.e. the participants will be analysed according to their randomized allocation, regardless of the actual interventions received by the patient. Results will be reported according to CONSORT guidelines, using the extension for non-inferiority trials. If necessary, skewed continuous variables will be transformed to normality prior to the analyses. Supplementary, we will perform per protocol analyses excluding participants in whom there is a clear deviation or suboptimal execution of the intended care as prescribed by the protocol in either the admission group or the telemonitoring group. Examples include technical difficulties at home or non-compliance of study agreements, cross-over, or participants in the telemonitoring arm with (multiple) hospital admissions accounting for over half of the study period.
The primary outcome, the composite (dichotomous) endpoint of perinatal mortality and morbidity will be analysed with logistic regression analysis with the stratification factors (centre of inclusion and diagnosis of pregnancy complication) and parity as pre-defined covariates in the regression model. No pre-specified subgroup analyses are planned.

Secondary outcomes
Each individual component outcome within the composite outcome will be reported as a single (secondary) outcome to provide further insight as the incidence and the relative importance between components of the composite outcome differ. Point estimates with confidence intervals for the comparison of groups will be reported for these components of the composite outcome.

Patient satisfaction and health related quality of life will be analysed with a general linear model for continuous outcomes. Comparison of questionnaires will be made for each time point, with the survey at 4 weeks post delivery being the most important. Assumptions for general linear model (i.e. normality, homoscedasticity) will be checked with residual analyses. In case of heteroscedasticity, the analyses will be repeated with robust (Hubert-White) estimators for standard errors. If distributional assumptions are violated, first a log transformation of the outcome will be analysed. If this transformation does not result in a valid regression analysis, intervention effects will be evaluated with a Mann-Whitney test without any corrections.

Time to delivery with account for different durations of gestation at study entry, will be evaluated with Cox regression with control of the stratification factors and parity as a predifned covariate.

For the cost-effectiveness analysis, all health care resources use will be transformed into cost estimates, by multiplying number of units of health care use, i.e. number of days in hospital, number of laboratory tests and other diagnostic tests with standard unit prices as provided by the Dutch guideline for costing research in health economic evaluation studies (National Health Care Institute, Zorginstituut Nederland, 2016). For medical costs, the process of care is divided into three cost stages (antenatal stage, delivery/childbirth, postnatal stage). Cost differences between the two treatment arms will be related to effect differences (primary outcome) between the treatment arms (if any). If non-inferiority of telemonitoring is confirmed, cost differences between the two treatment arms will be analysed (cost-minimization analysis). The cost effectiveness analysis will be performed from both the healthcare perspective and the societal perspective.

Study monitoring and safety

To monitor the conduct of the trial and safeguard the interest of participants, an independent Data Safety Monitoring Board (DSMB) will be established, including a professor of biostatistics, an obstetrician and a neonatologist. A study monitor will periodically visit participating centres, assessing quality of data and auditing trial conduct. All serious adverse events, reported by either participant or local clinician, will be recorded, and reported to the accredited ethics committee and the DSMB following international GCP guidelines. Trial data will be analysed and stored in the UMC Utrecht (study sponsor). No formal interim analysis of efficacy outcome is planned.

Ethics and dissemination

This trial has been approved by the Medical Research Ethics Committee (MREC) of the UMC Utrecht. Trial reference number: 16-516. The MREC of the UMC Utrecht is accredited by the Central Committee on Research Involving Human Subjects (CCMO) since November 1999. Approval by the boards of management of Amsterdam University Medical Center, Diakonessenhuis Utrecht, OLVG Amsterdam, Martini Ziekenhuis Groningen and St. Antonius

Ziekenhuis Nieuwegein is obtained prior to study start in each centre. Changes to the study protocol are documented in amendments and submitted for approval to the MREC. After completion of the trial the principal investigator will report on the results of the main study and submit a manuscript to a peer-reviewed medical journal. Supplementary analyses will be reported separately.

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CHAPTER 11
SUMMARY AND GENERAL DISCUSSION

SUMMARY

In this thesis, we aimed to explore the use of digital health tools in different pregnancy care paths.

Chapter 1 introduces the emergence of digital health and specifically telemonitoring in the obstetric care in the Netherlands.

In **chapter 2**, we describe the results of the literature research of the present knowledge on eHealth use in perinatal care. It includes users' characteristics and domains such as diabetes care, mental health and telemonitoring. Despite the promising preliminary results as presented, we accentuate the need for evidence for health outcomes, patient satisfaction, and the impact on costs of the possibilities of eHealth interventions in perinatal care. In general, the combination of increased patient empowerment and home pregnancy care could lead to more satisfaction and efficiency.

In **part I of the thesis** we report the development of a digital telemonitoring platform for women at risk of hypertensive complications.

In **Chapter 3**, we describe a validation study of two automated blood pressure monitors with Bluetooth for the connection with a smartphone application. Both the iHealth Track and the OMRON HEM-9210T were validated in a group of 33 pregnant women with use of the 2010 protocol of the European Hypertension Society. The group consisted of women with and without hypertension. The Bluetooth functionality of both monitors can link to our telemonitoring platform for use in pregnancy.

Chapter 4 shows the feasibility study of our telemonitoring platform, consisting of a smartphone application and connected BP monitor. This platform was tested in a group of low-risk pregnant women, without risk factors for hypertension. The objective was to assess participant compliance, efficacy of the automatic alert system and the usability and user satisfaction of the platform. Use of a digital platform for telemonitoring of blood pressure and preeclampsia symptoms was found feasible with good compliance, 93% and 85% for blood pressure and symptom checklists respectively. The majority of participants were satisfied with the system.

In **Chapter 5** we assessed the effects of our telemonitoring platform in women at high risk for hypertensive complications in pregnancy. We compared a prospective cohort of pregnant women (n=103) with telemonitoring and a predefined reduced antenatal visit schedule to a retrospective cohort (n=133) of women managed with usual care, without self-monitoring of blood pressure. Outcomes of interest were healthcare consumption, user

experiences and maternal and neonatal perinatal outcomes. Our research with this platform for women at risk of hypertension showed lower health care consumption (antenatal visits and hypertension-related admissions) of pregnancy care. In our sample, no increase of adverse events in pregnancy were observed. Therefore, telemonitoring has the potential to profoundly change antenatal care.

In **Chapter 6** we describe the economic evaluation of the results of the digital health study in Chapter 5. Costs of pregnancy care, including visits, ultrasounds, admission, laboratory tests were calculated, as well as societal costs such as travel costs and work absence. As a result of the reduction in health care consumption, use of the digital platform was associated with a 20% cost reduction in antenatal care. (median €3616 [IQR 3071 – 5329] vs €4504 [IQR 3515-6923], p=0.001). Total costs per pregnancy, including societal costs, were also reduced (€7485 [IQR 6338 - 10,173] vs €9150, [IQR 7546 - 12,286] p<0.001). Each euro invested in the platform saved on average €8 of antenatal care resources.

Furthermore, we explored the experiences, motivations and recommendations of users of our platform in a mixed-methods study (**Chapter 7**), which resulted in a number of best practices and recommendations for future implementation of digital health technologies. Surveys of 52 SAFE@HOME participants and 11 interviews resulted in analysis in 4 themes: 2 themes were related to the technologies themselves (expectations, usability), and 2 themes were related to the interaction and use of digital health (autonomy and responsibilities of patients, responsibilities of health care professionals).

In **part II**, our research focused on pregnant women with complications requiring daily fetal and maternal monitoring. To compare standard hospital admission with telemonitoring of cardiotocography and blood pressure from home, we performed different studies in order to increase knowledge of this use of digital health for complicated pregnancies.

In **Chapter 8**, we describe the experiences of pregnant women during either hospital admission because of pregnancy complications (n=11), opposed to women who participated in a pilot with telemonitoring (n=11). In this focus group study, women with cardiotocography at home expressed less feelings of boredom, anxiety or lack of privacy compared to women during hospital admission. Telemonitoring of a high-risk pregnancy provides an innovative manner to monitor fetal and maternal condition from home. Compared to the experiences of hospital admission in high risk pregnancy, it allows women to be in a comforting and private environment during an anxious time in their lives.

Chapter 9 is the report of a nationwide survey to all Dutch obstetric departments to determine the number of centres that provide home- and telemonitoring, and to identify the current practice of out-of-hospital care in high-risk pregnancy. In 2018, 38% (28/73)

of centers in the Netherlands offered either home-based monitoring or telemonitoring or both to pregnant women with complications. Home-based monitoring was offered in 26% (19/73) of the centers; telemonitoring, in 23% (17/73); and both in 11% (8/73). Both are provided for a wide range of complications, such as fetal growth restriction, pre-eclampsia, and preterm rupture of membranes. The respondents reported advantages of monitoring from home, such as reduced stress and increased rest for patients, and reduction of admission and possible reduction of costs. The stated barriers included lack of insurance reimbursement and possible technical issues.

Last chapter of this part is the protocol of a randomized controlled trial to study the new strategy: Hospital care versus TELemonitoring in high risk pregnancy – the HOTEL trial (**Chapter 10**). This multicentre randomized controlled trial aims to compare telemonitoring at the patient's home versus hospital admission with regard to perinatal outcome, patient satisfaction, preference of care and cost-effectiveness.

GENERAL DISCUSSION

In this chapter, we will discuss additional considerations regarding previous described findings and use of digital health in pregnancy and childbirth care, in the context of:

- safety,
- user experiences,
- shift into digital care,
- value-based care.

Also, implications for future use and research will be addressed.

Safety of digital health in obstetric care

The development of technological innovations and its implications for digital health may provide solutions for the need to optimize prenatal care. However, patient safety of digital health needs to be researched more extensively. Although there are clear examples of health benefit associated with digital health use, questions remain.[1]

Blood pressure telemonitoring; what is known

In the SAFE@HOME study, we studied the combination of symptom reporting and blood pressure measurements in women with (increased risk of) hypertension in pregnancy. Given the importance of accurate blood pressure measurements, especially in pregnancy because of changes in maternal hemodynamics, international societies have published several protocols to validate BP monitors.[2] These validation protocols are developed to ensure that the accuracy of new to use BP monitors is comparable to a gold standard measuring device. In a recent systematic review of accuracy of devices for use in pregnancy, 41 articles were identified, assessing 28 devices. In 61% the device was validated using a standard or modified protocol and only 34% of validated devices (11/32 studies), the validation study was performed without a protocol violation of modification.[3] Because of the implications of (in)accurate BP measurements on medical decision making, we validated two BP monitors in a pregnant population using the ESH protocol (Chapter 3). Both the iHealth Track and Omron HEM-9210T, chosen because of their Bluetooth connectivity for use in an adjacent smartphone application, were validated for use in a pregnant population with and without hypertension and preeclampsia. As prenatal care is integrating mobile technology more and more, these validated monitors may contribute to remote monitoring in pregnancy. Moreover, a recent individual patient data meta-analysis compared clinic readings with self-monitored BP measurement of 758 pregnant subjects and found an insignificant difference between those two. This evidence is helpful to determine thresholds of alarms for women who self-monitor BP during pregnancy.[4]

Subsequently, we developed a digital health platform for repeated measurements of BP and symptoms. Before its use in our intended population, we needed to assess several questions:

Does the platform meet the defined technical specifications, such as connectivity? Is the alert system accurate and free of errors? Is the system usable by the end-users and does it fit within their workflow?[5] Therefore we performed a so-called feasibility study (Chapter 4). Once established the platform's usability and feasibility, we could continue our studies to measure impact and observed changes in outcome, and attribute these to the digital health platform.

Results of our SAFE@HOME studies show that telemonitoring of blood pressure and preeclampsia symptom is feasible in a high-risk pregnant population. The use of the digital platform, combined with a reduced antenatal visit schedule was associated with a reduction of health care consumption, without compromising perinatal outcomes in our selected study population. Other recent studies describe a variety of home- and self-monitoring blood pressure strategies.[6-9] In general, most studies find a reduction in clinic visits and/or admissions, with help of out-of-office measurements. At the same time, this shift to home-based care in this risk group up to now does not seem to have a negative effect on pregnancy outcomes, such as incidence of preeclampsia, severe hypertension, mode of delivery and neonatal outcomes. However, in this field of digitally enhanced prenatal care, no randomized controlled trials of sufficient sample size have been conducted yet. The available evidence is mostly derived from underpowered retrospective or prospective cohort studies.

Telemonitoring of maternal and fetal condition: what is known

A solid technical infrastructure is required before research of digital health innovation in clinical settings. As found in our literature review, multiple devices and integrated systems are developed lately for wireless fetal monitoring from a distance.[10-13] Telemonitoring of cardiotocography has the potential to increase access to care, i.e. in rural areas, or to replace traditional monitoring in the hospital to a home setting. In the Netherlands, self-recorded cardiotocography is available with specially designed systems. Tracings are saved using Bluetooth and a tablet computer and sent to the hospital for the health care provider. Several systems have been tested in published studies for functionality, acceptability and usability.[14-17] Three pilot studies from both high and low income countries found the system to be acceptable for pregnant women and HCPs, and clinically useful. They describe its potential for use of telemedicine of maternity unites in underserved areas, as well as for inpatient settings, which has to be tested in feasibility studies.

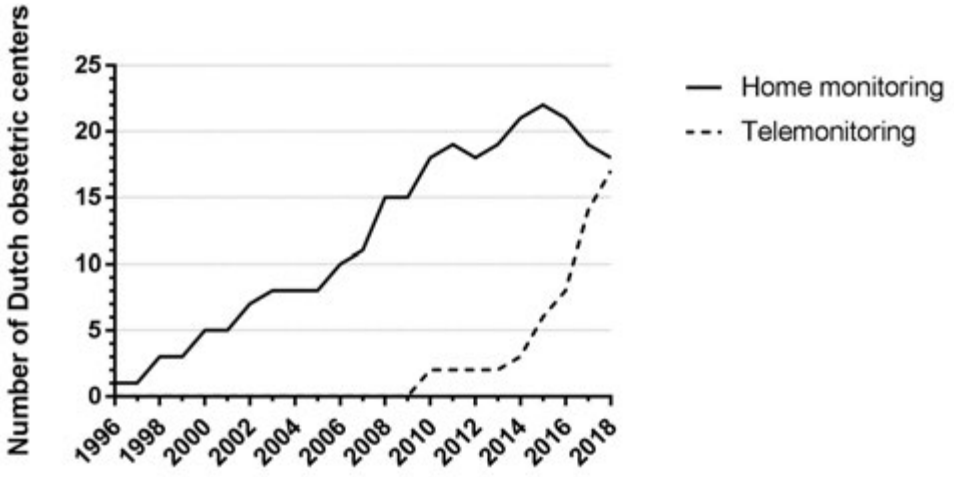
Before the start of a telemonitoring pilot, we compared fetal heart rate tracings with our general hospital equipment and found similar tracings. In the setting of the HOTEL trial high-risk pregnant women are trained by midwives to use the system at home. Separate from the hospital's own electronic health record system, the data are visible for health care providers in a secured web-portal. Since recently it is possible to integrate the tracings into general electronic health record software. This integration is beneficial for a more secured way of communication if the system is to be used on a large scale. As the tracings are visible within one single system, this integration enhances daily medical decision making.

Risks of early, unevaluated implementation of digital health

There is paucity of data on telemonitoring of fetal condition in high-risk pregnancy (Chapter 2 and Chapter 10). To date, no prospective or randomized controlled trials are performed to assess clinical and cost-effectiveness or perinatal outcomes of a monitoring strategy using home cardiotocography tracings. While multiple systems are (being) developed and tested for feasibility and usability, safety issues remain unclear. Our research group favours innovation of care, using telemedicine, for the pregnant population. Therefore, we are strongly committed to evaluate its impact before wide implementation in clinical practice. Possible risks associated with early implementation of unevaluated digital health include usability problems, issues regarding safety and reimbursement, and possible adverse perinatal outcomes, resulting in disappointing adoption by the end-users.

To compare safety, satisfaction and cost-effectiveness of traditional HOspital care versus daily TELemonitoring at home for complicated pregnancies; we set up the multi-center randomized controlled HOTEL trial (Chapter 10). Pending the fulfilment of inclusions of our on-going trial in 6 Dutch obstetric units, a number of hospitals choose to implement telemonitoring as standard care for high-risk pregnancy. We performed a survey in December 2018, which revealed that 17 hospitals (representing 23% of all 73 hospitals offering obstetric care in The Netherlands) now work with pregnancy telemonitoring (chapter 9). Of these 17 centers, 59% reported they have never performed an evaluation of results before implementation in practice, while the other participate in the trial. Figure 1 shows that the use of pregnancy telemonitoring continues to grow, yet without proven value and safety for the patient.

Figure 1 Trend graph of Dutch centres offering home- and telemonitoring in high-risk pregnancy.



Future studies

Unanswered questions remain on blood pressure telemonitoring in high-risk or hypertensive pregnancies. There is a need for studies elucidating the effects of telemonitoring in early detection of complications, rare adverse perinatal outcomes, prevention of severe hypertension and decision making on early interventions. Therefore, (more) large prospective trials are necessary. Randomized trials must be adequately sized to assess if self-monitoring in pregnancy can improve the detection of raised blood pressure and its consequences on perinatal outcome.[18-19] The UK-based BUMP project conducts two linked multicentre RCTs: one for women at higher risk of hypertension in pregnancy, and one for women with chronic or gestational hypertension. The interventional arm starts with self-monitoring of blood pressure around 2 weeks of gestation but without in-hospital monitoring of results / alarms. Primary outcomes for the study's sample size calculation are: time to first raised blood pressure and change in mean blood pressure between baseline measurement and delivery. Secondary outcomes include maternal and perinatal outcomes as well as process and costs evaluations. As inclusion of the BUMP trials is completed with almost 2800 participants, we are looking forward to the results. In the meantime, a large prospective implementation study of the SAFE@HOME strategy will be performed in the Netherlands. This study will evaluate medical outcomes as well as qualitative data to enable the development of the best possible implementation strategy on a national scale. This includes viewpoints of health care provides as well as patients.

For telemonitoring of maternal and fetal condition in complicated pregnancies, the results of the HOTEL trial will report on perinatal safety, amongst others. As most studies on telemonitoring in high-risk pregnancy, the HOTEL trial will also be proven to be underpowered to assess adverse maternal, fetal and neonatal outcomes. Therefore, future prospective studies must demonstrate the effects of digital technology in the light of evaluation of (rare) adverse events in perinatal care. In recent years, questions arise around the design of randomized-controlled trials, as it can possibly not keep up with the speed of innovation.[20] However, robust evidence remains highly relevant. Traditionally, the RCT is considered the gold standard for efficacy evaluation. As RCTs study highly selective populations, and are managed in a tightly controlled setting, those may fail to represent a wider population or "real-world-medicine". Inclusion of a control arm, especially in digital health research, may become difficult as personalized medicine becomes increasingly common, affecting participant recruitment for RCTs. Moreover, other drawbacks of RCT's are extensive costs and time needed for preparations, data collection and analysis. The feasibility of conducting large RCTs in pregnant women is therefore questionable for multiple reasons.

User experiences of digital health in obstetric care

The most important objectives in digital health evaluation are: What are our users' needs that we can possibly address with digital health? What is the target population I aim to influence with my innovation? How will the participants adopt the tool and how do they interact with technology? To collect information on patient views of digital health in pregnancy, and to use their views in research and prenatal care, we used 3 different methods: a review of existing literature, a feasibility study, and a mixed-methods approach to describe experiences of women who used our digital health platform (chapters 2, 7 and 8).

Presently, pregnant women are 'digital natives'. Therefore, they are equipped with the hardware to send measurements and the mind-set to communicate digitally with their health care provider. Results of previous literature reflect this general view: women report that platforms for home measurements are easy to use and the time involved fits into their daily routine. These applications and platforms enable transmission of data in the electronic patient file in het hospital to monitor abnormal values from a distance.[6,21,22] In this way, home data can facilitate shared decision making between patient and care provider. Pregnant women consider the medical professional's expertise indispensable to oversee the needed actions in management and feel relieved that the monitoring is not solely the patient's responsibility. Based on our participants' insights, we made a set of recommendations for future development and implementation of digital health care, which are represented in Chapter 7. In summary, digital health innovations are regarded as useful for participants if they provide insights in data in forms of graphic representations with personalized surveys and thresholds. When integrated in usual care, participants feel the health care provider is responsible for detection of abnormalities and making clinical decisions.

Insights in the experiences of pregnant women are important to ensure future care will be based on the individual patient's perspective, preferences and needs. Findings from previous studies and our Facebook focus group study (Chapter 8) reveal that telemedicine may provide important psychological benefits during pregnancy.[23] When women's perception of high risk pregnancy and quality of care experience improve with telemonitoring, this may contribute to better quality of life and reduction of antenatal anxiety and its consequences for mother and child.

On the shift from hospital admission to home-based telemonitoring, the experiences of participants provide some recommendations for implementation from the patient perspective (Chapter 8): these include the demand for patient education and a clear antenatal management plan, adequate participant selection for telemonitoring, daily contact (by telephone or teleconferencing) by a select group of staff for a continuum of care (as our Obstetric Telemonitoring Team) and weekly hospital visits. As long as conclusive data on the clinical safety of telemonitoring in high risk or complicated pregnancy are lacking, we recommend to use strict protocols for care providers and patients, and to allow only limited

travel time and distance from the patient's home to the hospital.

We acknowledge that more information on the viewpoint and experience of obstetric professionals on digital health care is needed. As professionals are end-users of telemonitoring services too, working with digital technologies will change their current practice profoundly. Medical decision making with use of home measurements will be part of their tasks in prenatal care, but to what extend to they feel comfortable with this role?

Digital transformation of healthcare in the Netherlands

It is widely known that the use of digital health is able to provide essential solutions to healthcare demands, such as staff shortages, rising healthcare costs and accessibility of care. However, developments come with challenges and successful uptake of digital care is not self-evident. The process that is required for successful uptake, requires a transformation within healthcare.[24]

In the Dutch eHealth-monitors, digitalisation of care is observed to progress at different speeds. What is the reason for the difference in development and actual implementation? And what can we learn from past initiatives? Two of the conclusions that can be drawn from evaluations in the field of Dutch health care: progress in digital health is currently limited by (a lack of) integrated data modalities and restrictions regarding social and cultural changes.[25] To what extend can this thesis add to the current limitations?

On the level of data integration: home measurements must be visible and accessible to transform into information for both users (patient and health care providers) which depends on the integration of separate information systems. We have addressed this important topic in Chapter 7 on user experiences of telemonitoring services. Action has to be taken on all levels (governmental, hospital institutions, registry services, insurance companies and the industry) to coordinate and integrate self-measured data from home to be of benefit for care – from individuals to population.

Digital health implementation is a result of a complex process of research and development, starting often with start-ups in the Life Science and Health sector. The Netherlands offer an international and innovative business climate for these efforts.[26] After successful product development, businesses need to connect with hospitals and clinics as end-users of their services. As seen in our research with digital health in pregnancy, both industry as well as research groups or clinicians are co-dependent of each other in this process. We worked with different companies and their products. As mentioned before, financial stability and the intention to co-develop are essential to overcome barriers such as data integration and future implementation.

On the level of cultural change: digital care requires a different way of working for health care providers and professionals in medicine. Implications of digital care include digital interaction between patient and professional, shared participation and better-informed and more active patients.[27] As such, the emergence of digital tools for information and remote

monitoring is assumed to reconfigure expertise of both patients and healthcare providers, with an impact on the relationship between them. These implications ask for trust in each other's expertise. Professionals should embrace the novelties of digital care, even if this means a shift of tasks from their traditional way of working. However, help of a clear vision and ambition of healthcare directors within different organisations is needed. On a positive note, the e-Health monitor of the Netherlands in 2019 showed an increase in the enthusiasm of care professionals of the use of e-Health and for the use of self-monitoring strategies specifically. Sixty percent of general practitioners and physicians experienced that telemonitoring promotes patient autonomy and quality of care.[28]

Value

In the light of the strategy of value-based care, this thesis can be seen as a pilot evaluation of both quality (i.e. perinatal outcome, experiences of participants) and cost of new telemonitoring models in both risk pregnancies and complicated pregnancies. Technology plays a big role in the rapidly changing healthcare landscape. Also, it facilitates the benchmarking and reporting of patient outcomes and care quality using data and analytics. Also, in pregnancy and childbirth care, including our research involving digital technology, the perspective of value-based healthcare has significant implications for future care delivery.[29] In perinatal health, the shift from traditional care to "appropriateness" of care is ongoing, resulting from a movement of systematically performed quality evaluations. However, underuse, overuse and misuse of medicine are to be avoided. Next to the provision of safe and effective care, it must be valuable for those who deliver, receive and pay for it.[30]

Figure 2. The actors in measuring value of care

Both quality and cost are actors in this value equation as postulated by Michael Porter and Elisabeth Olmsted Teisberg (Figure 2).[31] Preferably, value is to be measured and increased in care cycles, with inclusion of patient-reported outcomes (PROMs) and integration of care of different facilities. Naturally, this comes with challenges: which outcomes should we focus on, and which patient-reported experience best reflects value in pregnancy care? And from our viewpoint, what is the role of digital advancements, such as telemonitoring? Digital health may contribute to the collection of PROMs, and eventually in the evaluation of pregnant women's needs in obstetric care.

A critical evaluation of emerging technologies in the field of prenatal care is necessary to determine its added value in future care models. This viewpoint is in line with the Dutch Health Ministries' program "Outcome based healthcare 2018-2022" stating four central objectives: more insight into outcomes, more shared- decision making, organisation and funding of care focused on outcomes; and better access to relevant and up-to-date outcomes information.[32] As a result of this program, multiple initiatives within pregnancy and childbirth care have been established. One of the examples, the BUZZ project, is conducted in pregnancy in seven regions in the Netherlands and aims to implement shared decision making with help of PROMs using the International Consortium of Health Outcome Measurement (ICHOM) Pregnancy and Childbirth standard outcome set.[33,34]

The field of pregnancy and childbirth care in the Netherlands promotes and advances integrated (birth) care.[35] Care is increasingly offered by a continuum of services, crossing the boundaries of the different compartments of primary, secondary of tertiary care. Evidence shows that integrated care reduces costs with improvement of quality of care and patient outcomes.[36] In general a shift of care to lower levels of specialization is observed: from (tertiary) hospital care, to general practioner, to practice nurse, of self-care. In the Netherlands this movement is known by the name "Right care at the right place". The use of digital health can aid in the downscaling of pregnancy care delivery too. With help of our digital platform, daily measurement from home are sorted by midwives and obstetric nurses, before abnormal results are to be evaluated by physicians. An integrated approach including telemonitoring in pregnancy can also result in more efficient, accessible and patient-friendly care.[37]

Future implications

Insights provided by this thesis on the results of digital care on perinatal outcomes, patient experiences and cost comparisons can be a starting point for future practice and research. In line with the triple aim of improvement of health care, a division can be made in to experienced quality of care, healthcare outcomes and impact on costs. In general, we found that the use of digital care can enhance the experienced quality of care perceived by pregnant women. The involvement of pregnant women in future care strategies on blended care seems essential for increased uptake and implementation in care. Therefore, in each stage of development, research or implementation, end-users must be actively engaged. Research with both quantitative and qualitative methodologies can provide valuable answers for tailored care.

To assess the participation of all stakeholders in a novel strategy of care enhanced with digital health, implementation science will play a crucial role. Future evaluations of implementing digital health will find barriers and facilitators from all perspectives (i.e. patients, care professionals, other hospital personnel, patient associations and financial experts). With help of the results of implementation research, future care can benefit from sustainable

blended care strategies that are supported by all stakeholders.

Secondly, future prospective studies, including the results of the HOTEL trial, must prioritize the effects of digital technology in the light of evaluation of safety, i.e. the risk for occurrence of (relatively rare) adverse events in perinatal care. Published studies on telemonitoring in high-risk pregnancy are underpowered to assess risk for (relatively rare) adverse maternal, fetal and neonatal outcomes. The effects of self- or home-measurements on medical and shared decision making on interventions such as medication use or induction of labor are not known. It will be very challenging to fill this knowledge gap. Large prospective cohort studies or randomized trials in populations of women with hypertension in pregnancy require considerable efforts by large consortia and substantial funding, questioning their feasibility.

Another trend in digital health is the use of wearables for selfmonitoring parameters such as physical activity, sleep, heart rate, condition etc. It is expected that in the Netherlands, 9 million wearables will be used in 2020.[26] Also in pregnancy, personalized monitoring of mentioned parameters can be useful for promotion of health lifestyle, well-being and sleep.[38,39] With the addition of the possibility to measure and monitor blood glucose, telemonitoring is also helpful in the care for pregnant women with (gestational) diabetes mellitus.[40]

Lastly, digital health provides opportunities for shared decision making in prenatal care. Patient counseling on test and treatment options within antenatal requires accurate information, for example in prenatal testing, vaginal birth after caesarean section or treatment in imminent preterm labor. Digital decision aids aim to help patients and their families to weigh benefits of different treatment options against their risks. To involve pregnant women in the decisional process, decisional aids need to be developed with use of the criteria from the International Patient Decision Aids Standards (IPDAS). Their uptake and effects of its use need be followed using implementation studies.

Concluding remarks

This thesis on digital health in obstetric care contributes to the knowledge on development and evaluation of tools for remote monitoring of both maternal and fetal parameters. The use of devices and smartphone applications for self-measurements and in-hospital monitoring provides an innovative manner of prenatal care for women with (risk of) complicated pregnancies. Our research underlines that pregnant women are members of 'Generation Z' and therefore willing to and capable of working with health tools for remote monitoring. The introduction of digital tools in pregnancy care may enhance appropriate use of resources and services, experience of care and hopefully also safety of care. We hope the results of this thesis will create opportunities for future development and use of digital tools in pregnancy. In a step-by-step approach, scientific evidence of digital care in pregnancy must ultimately lead to highest-value perinatal care, tailored to the needs of pregnant women and obstetric care professionals.

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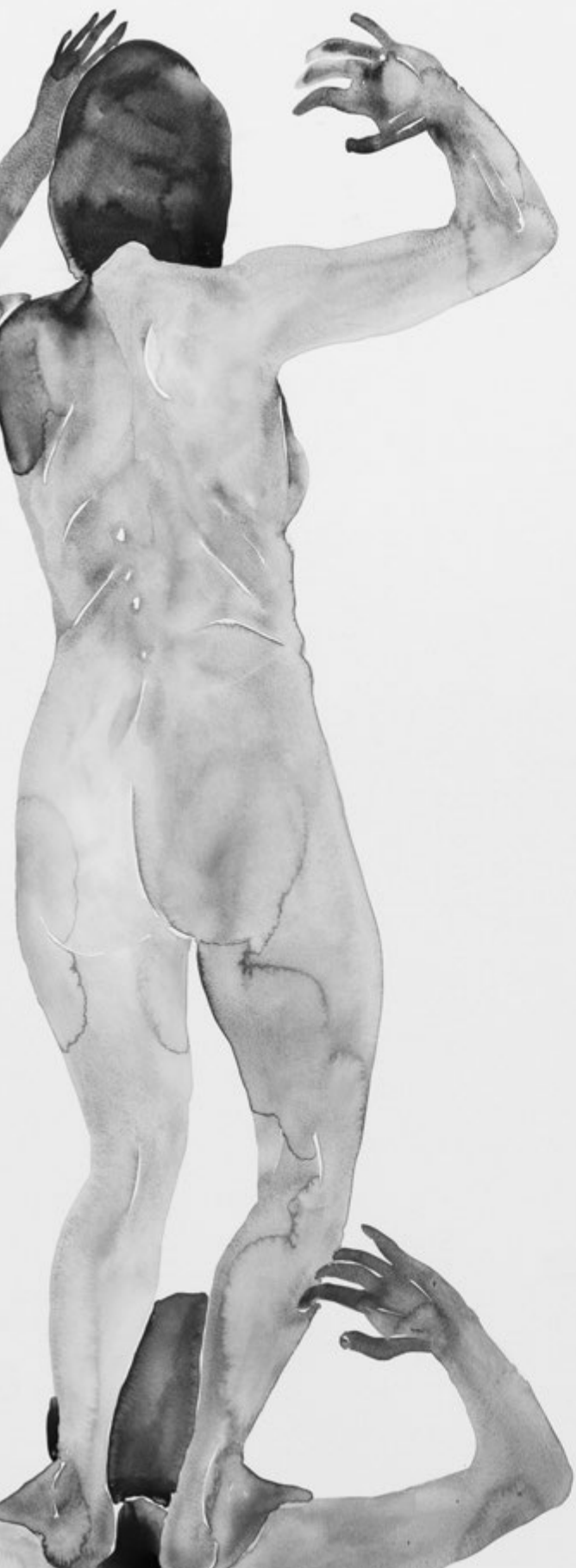

ADDENDA

NEDERLANDSE SAMENVATTING (DUTCH SUMMARY)

LIST OF PUBLICATIONS

COVER ART

DANKWOORD (ACKNOWLEDGEMENTS)

ABOUT THE AUTHOR

NEDERLANDSE SAMENVATTING

Proefschrift: Digitale toepassingen in de verloskundige zorg

De opkomst van digitale zorgtoepassingen kan bijdragen aan de verbetering van zorg voor zwangeren met (risico op) gecompliceerde zwangerschappen. In dit proefschrift exploreren we verschillende aspecten die van belang zijn bij digitalisering van de verloskundige zorg.

In **hoofdstuk 1** van dit proefschrift introduceren we de thema's van digitale zorg en zwangerschapscomplicaties. Om complicaties tijdens de zwangerschap te diagnosticeren en te monitoren, zijn frequente ziekenhuisbezoeken nodig om de maternale en foetale conditie te controleren. Voorbeelden van complicaties zijn hypertensie, foetale groeirestrictie, diabetes en vroeggeboorte. Ongeveer 10% van de zwangeren ontwikkelt een hypertensieve aandoening in de zwangerschap, zoals preëclampsie. Voor zwangeren met een hoger risico op het ontwikkelen van hypertensie kan de frequentie van antenatale bezoeken variëren van eens in de twee weken, oplopend tot 3 keer per week. Deze bezoeken interfereren met hun dagelijks leven en kunnen belastend zijn voor de zwangere als ook haar familie en vrienden. In de zoektocht naar verbetering van zorg voor zwangeren met (risico op) complicaties, kan de opkomst van digitale zorg oplossingen bieden. In dit proefschrift wordt gebruik gemaakt van drie termen: Thuismonitoring is thuiszorg voor zwangeren waarbij ziekenhuispersoneel bij de zwangere thuis langs gaat om aanvullend onderzoek in te zetten (zoals bloeddruk, cardiotocografie (CTG) of bloedafname). Zelfmonitoring is de term die gebruikt wordt voor metingen, die door patiënten thuis zelf verricht worden; bij afwijkende waarden (van bijvoorbeeld bloeddruk) neemt hij/zij contact op met de zorgverlener. Telemonitoring is een geavanceerdere vorm van digitale zorg waarbij thuismetingen van patiënten worden verzonden naar de zorgverlener, die vervolgens contact op kan nemen met de patient en acties kan inzetten bij afwijkende (drempel)waarden.
Ook in antenatale zorg worden verschillende vormen van digitale zorg toegepast in 6 verschillende domeinen: informatievoorzieningen, leefstijlverbetering, diabeteszorg, geestelijke gezondheidszorg, telemonitoring en in lage- en middeninkomenslanden. Vele zwangeren zijn in het bezit van een smartphone en gebruiken apps voor informatie over hun zwangerschap. Zij waarderen informatie die zij vinden op internet als redelijk betrouwbaar en bespreken deze met hun zorgverlener. Deze informatie over de opstelling van zwangeren tegenover digitale zorg hebben we gebruikt als de basis voor dit proefschrift. In twee delen onderzochten wij in welke vorm digitale zorg kan bijdragen aan de zorg voor gecompliceerde zwangerschappen.

In **hoofdstuk 2** verzamelden we alle beschikbare onderzoeken over het gebruik van digitale zorg voor zwangeren in een literatuurstudie. Deze studie leverde 71 studies op. Deze studies werden gecategoriseerd in de eerdergenoemde zes domeinen. Studies over

zwangerschapsdiabetes en geestelijke gezondheidszorg laten zien dat digitale zorg goede alternatieven zijn voor standaard zorg. Ook kunnen apps en onlineprogramma's leiden tot minder gewichtstoename, meer beweging en minder roken in de zwangerschap. Verschillende studies beschrijven systemen voor foetale telemonitoring met CTG en uterusactiviteit; echter zijn er maar weinig studies die uitkomsten beschrijven die van belang zijn voor de zorg, zoals veiligheid en effectiviteit. Patiënten en zorgverleners zijn over het algemeen tevreden met deze nieuwe strategieën die zorgen voor een verplaatsing van ziekenhuis-georiënteerde naar patiënt-georiënteerde zorg. Ondanks de veelbelovende allereerste inzichten concludeerden we dat meer onderzoek nodig is naar de impact van digitale zorg op onder andere veiligheid, kosten en tevredenheid bij gebruik in de zwangerschap.

Deel I Telemonitoring voor zwangeren met een verhoogd risico op preëclampsie

In het eerste deel beschrijven we de rol van telemonitoring van thuismetingen van bloeddruk en klachten bij zwangeren met een risico op het ontwikkelen van preëclampsie. Telemonitoring kan een belangrijke rol spelen bij de verplaatsing van ziekenhuiszorg naar zorg vanuit huis om zo de zwangerschapsbegeleiding te verbeteren. We ontwikkelden een digitaal platform voor de uitwisseling van thuismetingen via monitoring in het ziekenhuis. Afwijkende waarden resulteren in alarmen in het dashboard voor zorgverleners, die vervolgens actie kunnen ondernemen voor aanvullend onderzoek naar onderliggende pathologie. Deel I beschrijft het ontwikkelproces en de evaluatie van dit digitale platform in de verschillende SAFE@HOME studies.

In **hoofdstuk 3** voerden we een validatiestudie uit van 2 bloeddrukmeters, de iHealth Track en de Omron HEM-9210T, in een populatie van 33 zwangeren met en zonder hypertensie. Er zijn vele automatische bloeddrukmeters beschikbaar en deze worden steeds meer gebruikt door patiënten, mede ook op aanraden van hun zorgverleners. Echter, slechts weinig meters zijn gevalideerd voor gebruik onder zwangeren. Accurate metingen van de bloeddruk zijn essentieel voor het diagnosticeren en controleren van de bloeddruk in de zwangerschap. In deze prospectieve observationele studie werd gebruik gemaakt van het gereviseerde 2010 protocol van de European Hypertension Society. Beide automatische bloeddrukmeters werden volgens dit protocol gevalideerd en geschikt bevonden voor gebruik in de zwangerschap. De Bluetooth-functionaliteit kan gebruikt worden om deze meters te koppelen aan ons digitale platform voor telemonitoring van bloeddruk.

In **hoofdstuk 4** beschrijven we een haalbaarheidsstudie waarin 14 laag-risico zwangeren gedurende 15 werkdagen hun bloeddruk en een klachtenvragenlijst doorstuurden. Samen met Luscii (Focuscura, Nederland) ontwikkelden we een digitaal platform dat bestaat uit een app of webportal voor zwangeren en een dashboard voor zorgverleners. Dit SAFE@HOME systeem maakt gegevensuitwisseling mogelijk voor monitoring van (gecompliceerde)

zwangerschappen. De participanten stuurden 93% van de gevraagde bloeddrukmetingen en 85% van de gevraagde klachtenvragenlijsten in. Zeven bloeddruk-alarmen (4% van alle metingen) werden afgehandeld door het studieteam en alleen bij een combinatie van afwijkende resultaten van bloeddruk en klachten was aanvullende zorg vereist. De tevredenheid over het gebruik van de app en de meter was goed. De resultaten van deze haalbaarheidsstudie waren goed en potentieel van toegevoegde waarde voor de zorg voor zwangeren met (risico op) hypertensieve aandoeningen.

Hoofdstuk 5 beschrijft het gebruik van het digitale platform SAFE@HOME in een groep zwangeren met een verhoogd risico op preëclampsie: zwangeren met essentiële hypertensie, een voorgeschiedenis van preëclampsie, of een maternale cardiale of nieraandoening. Prospectief werd een groep van 103 zwangeren uit 2 ziekenhuizen gevolgd tijdens het gebruik van SAFE@HOME met bloeddrukmetingen op doordeweekse dagen. De metingen werden in het ziekenhuis bekeken door het telemonitoring-team, dat bij afwijkende waarden contact opnam met de gynaecoloog en de patiënt indien (poli)klinische evaluatie nodig was. Tegelijk met het gebruik van het platform werden de zwangeren gecontroleerd met behulp van een zorgpad met minder geplande poliklinische bezoeken. In deze case-control studie werd de prospectieve SAFE@HOME groep vergeleken met een groep zwangeren (controle groep, n=133, uit 2015-2016) die geen gebruik maakten van telemonitoring in de zwangerschap. De SAFE@HOME strategie bleek geassocieerd met minder antenatale (poliklinische) afspraken en minder echo-afspraken. Daarbij waren er minder hypertensie-geassocieerde opnames in de SAFE@HOME groep. Er was geen verschil in maternale of perinatale uitkomsten, zoals optreden van preëclampsie, medicatiegebruik, manier van bevallen of termijn en gewicht bij geboorte. We concludeerden dat deze resultaten wijzen op de haalbaarheid van telemonitoring in een hoog-risico populatie zwangeren. Hierbij heeft telemonitoring de potentie om de antenatale zorg betekenisvol te kunnen herinrichten. Aanvullende onderzoeken zijn noodzakelijk om de impact van telemonitoring op vroege detectie van complicaties en de gevolgen hiervan te beschrijven.

Aanvullend aan de SAFE@HOME studie beschrijft **hoofdstuk 6** een kostenanalyse om de innovatieve strategie te vergelijken met standaardzorg zonder telemonitoring in de zwangerschap. Hiervoor zijn de kosten per zwangerschap berekend van 97 zwangeren in de SAFE@HOME groep en 133 in de controle groep. Alle zwangeren hadden een verhoogd risico op preëclampsie: vanwege essentiële hypertensie, een voorgeschiedenis van preëclampsie, of een maternale cardiale of nieraandoening. De kosten van ziekenhuisbezoeken, echo's, opnames en laboratoriumonderzoek werden aangevuld met maatschappelijke kosten van werkverzuim en reiskosten voor de ziekenhuisbezoeken. De kosten voor gebruik van het platform werden tevens meegerekend. Het gebruik van het SAFE@HOME platform voor telemonitoring, in combinatie met een gereduceerd zorgpad, was geassocieerd met minder polikliniekbezoeken, echo's en hypertensie-gerelateerde opnames. Deze

resultaten van minder zorgverbruik leidden tot een significante reductie van de zorgkosten per zwangerschap met 19,7% (van 4504 euro naar 3616 euro [mediaan]). Wanneer de kosten van werkverzuim en reizen hierbij worden opgeteld, daalden de totale kosten per zwangerschap van 9150 euro naar 7485 euro (18.2%). Iedere euro die werd gebruikt voor het SAFE@HOME platform leidde tot een kostenreductie van 8 euro door het gebruik van minder zorg. Omdat de perinatale uitkomsten in beide groepen vergelijkbaar waren, is deze digitale zorgtoepassing een veelbelovend middel om antenatale zorg te verbeteren en kosten te verlagen.

Er is nog weinig informatie bekend of telemonitoring van bloeddruk en klachten ook goed wordt ervaren door de gebruikers, in onze studie de zwangeren met een verhoogd risico op preëclampsie. We hebben daarom in **hoofdstuk 7** deelnemers aan de SAFE@HOME studie bevraagd naar hun ervaringen, verwachtingen en voorkeuren over het gebruik van het digitale platform. Uit de analyse van vragenlijsten en interviews kwamen 4 thema's naar voren: verwachtingen, gebruiksgemak, verantwoordelijkheid en autonomie van de patiënt als gebruiker en de verantwoordelijkheid van de zorgverlener als gebruiker van het platform. Het platform voldeed aan de verwachtingen van de patiënten, wat bijdroeg aan hun tevredenheid in het gebruik hiervan. Ten tweede noemden zij het platform gebruiksvriendelijk, alhoewel zij soms meer inspraak in frequentie en moment van meten zouden willen. Door de inzichten in hun eigen bloeddruk en klinische conditie voelden zij zich meer betrokken in de zorg en voelden zij zich bekwaam om samen beslissingen te maken over hun zwangerschap. Daarnaast noemden zij de expertise van de zorgverleners wel als essentieel voor deze manier van zorg; zowel om data te interpreteren als om hierop beleid aan te passen. De inzichten die we verkregen in deze studie hebben we gevat in 7 aanbevelingen voor het ontwikkelen en interpreteren van vergelijkbare digitale interventies.

Deel II Telemonitoring van zwangeren met zwangerschapscomplicaties

In het tweede deel beschrijven we de rol van telemonitoring van cardiotocografie (CTG) bij zwangeren met indicatie voor dagelijks CTG voor foetale monitoring. In de huidige vorm van antenatale zorg in Nederland zijn dit zwangeren met een opname-indicatie op een ziekenhuisafdeling. Ook hier kan telemonitoring een rol spelen bij de verplaatsing van ziekenhuiszorg naar zorg vanuit huis. Deel 2 beschrijft de studies naar ervaringen van zwangeren en Nederlandse klinieken met het gebruik van CTG-telemonitoring. Het sluit af met het protocol voor de HOTEL studie: een multicenter gerandomiseerde studie naar hospital admission versus telemonitoring in hoog-risico zwangerschappen.

Ziekenhuisopname in de zwangerschap is een impactvolle gebeurtenis. Innovaties zoals telemonitoring van foetale CTG kunnen van waarde zijn voor gebruik bij gecompliceerde zwangerschappen. We hebben in **hoofdstuk 8** een focusgroepstudie opgezet met gebruik

van Facebook-groepen met 11 zwangeren die zijn opgenomen in de zwangerschap, en 11 zwangeren die met telemonitoring vanuit huis hun zwangerschap hebben gecontroleerd. De vragen en antwoorden op de Facebook-groepen leiden tot 4 hoofdthema's: ervaring van verkregen zorg, emoties over het verloop van de zwangerschap, privacy en impact op het dagelijks leven. De meeste zwangeren die opgenomen waren geweest, rapporteerden een toenemend gevoel van zowel verveling als angst tijdens hun opname. Tevens was er een groot gebrek aan privacy op de afdeling, wat hun contact met ziekenhuispersoneel als ook hun naasten negatief beïnvloedde. Dit probleem kenden telemonitoring-participanten niet. Deze vrouwen voelden zich thuis nog wel af en toe patiënt maar noemden vooral de voordelen van thuis zijn, zoals hun eigen bed en comfort, en familie en vrienden altijd in de buurt. Slechts een kleine minderheid van telemonitoring patiënten was soms angstig thuis, omdat er niet direct een verpleegkundige of arts in de buurt zou zijn. Vergeleken met ziekenhuisopname kunnen vrouwen met behulp van telemonitoring dus verblijven in hun comfortabele thuisomgeving in een al spannende periode van hun zwangerschap. Deze ervaringen van zwangeren zijn van groot belang voor implementatie van digitale zorgtoepassingen. Toekomstige studies zullen zich moeten richten op aspecten zoals veiligheid en kosteneffectiviteit van deze innovatieve manier van zwangerschapsbegeleiding.

Hoofdstuk 9 toont de resultaten van een landelijke enquetestudie onder zorgverleners. Alhoewel telemonitoring van zwangeren met een opname-indicatie al wel enkele jaren wordt toegepast, is er tot op heden weinig bekend over deze strategie, de indicaties en de redenen voor het gebruik van telemonitoring. Antwoorden op deze vragen zijn relevant voor clinici die telemonitoring in de zwangerschap overwegen in te zetten op hun afdeling. Van 78% (57 van de 73) van de Nederlands verloskunde-afdelingen hebben we antwoorden gekregen op deze vragen. Thuismonitoring met behulp van thuisbezoeken wordt ingezet in 26% van alle ziekenhuizen en telemonitoring met zelfmeting van CTG in 17 ziekenhuizen (23%). Hiervan participeerden 6 centra in de HOTEL studie, echter de overige centra zijn gestart met telemonitoring zonder evaluatie van relevante uitkomsten zoals veiligheid of gebruikerstevredenheid. Thuis- en telemonitoring wordt gebruik voor een breed scala aan complicaties zoals groeirestrictie, preëclampsie, prematuur gebroken vliezen. Zorgverleners rapporteerden vele voordelen voor patiënten zoals minder stress en angst, meer rust thuis, en tevens afname van opnames en mogelijk dus ook kosten. Genoemde barrières voor gebruik van telemonitoring zijn het gebrek aan vergoeding van verzekeraars en mogelijke technische problemen.

Hoofdstuk 10 beschrijft het studieprotocol voor de HOTEL studie: een multicenter gerandomiseerde non-inferiority studie naar *HOspital admission versus TELemonitoring in hoog-risico zwangerschappen*. Mogelijke deelnemers zijn zwangeren >26 weken met een indicatie voor dagelijkse monitoring vanwege preëclampsie, foetale groeirestrictie, prematuur gebroken vliezen zonder contracties, herhaaldelijk minder leven voelen of een

intra-uteriene vruchtdood in de voorgeschiedenis. Zij worden gerandomiseerd tussen ziekenhuisopname met standaardzorg ofwel telemonitoring waarbij zij dagelijks zelf thuis een CTG maken met Sense4Baby monitor en bloeddruk kunnen meten met een Microlife meter. Vervolgens vindt dagelijks contact plaats tussen verloskundig zorgverlener en participant om de resultaten door te nemen en beleid te bespreken. Primaire uitkomstmaat is een samengestelde uitkomstmaat van perinatale mortaliteit, Apgar van 5 minuten onder de 7 of navelstrengarterie pH onder 7.05, maternale morbiditeit (eclampsie, HELLP syndroom of trombo-embolisch event), NICU opname en sectio caesarea aantal. Patiënttevredenheid en voorkeuren worden gemeten met behulp van gevalideerde vragenlijsten. Tevens zal een economische analyse worden uitgevoerd.

Tot slot bespreken we in het laatste **hoofdstuk 11**, de discussie van het proefschrift, de belangrijkste bevindingen in het licht van 5 aanvullende overwegingen: de veiligheid van digitale zorg in de zwangerschap, ervaringen van gebruikers van digitale zorg, de verschuiving naar meer digitale zorg in Nederland, digitale zorg in het kader van waardegedreven zorg en aanvullende implicaties en toekomstige trends.

Concluderend draagt dit proefschrift bij aan de kennis van ontikkeling en evaluatie van maternale en foetale telemonitoring. Het gebruik van apps en apparatuur voor zelfmetingen en telemonitoring vormt een innovatieve manier van prenatale zorg voor vrouwen met (risico op) zwangerschapscomplicaties. Ons onderzoek onderstreept dat zwangeren bereid zijn om met deze digitale toepassingen te werken. De introductie van digitale toepassingen kan zinnige zorg doen toenemen, en ervaringen en mogelijk ook veiligheid in de zorg doen verbeteren. We hopen dat de resultaten van dit proefschift kansen zullen creeeren voor toekomstige ontwikkelingen op dit gebied. Wetenschappelijk onderzoek naar digitale zorg in de verloskunde moet uiteindelijk leiden tot hoogwaardige perinatale zorg, afgestemd op de wensen van zwangeren en hun zorgverleners.

LIST OF PUBLICATIONS

SAFE@HOME: Cost analysis of a new care pathway including a digital health platform for women at increased risk of preeclampsia
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Accepted for publication in Pregnancy Hypertension

Home-Based Monitoring and Telemonitoring of Complicated Pregnancies: Nationwide Cross-Sectional Survey of Current Practice in the Netherlands.
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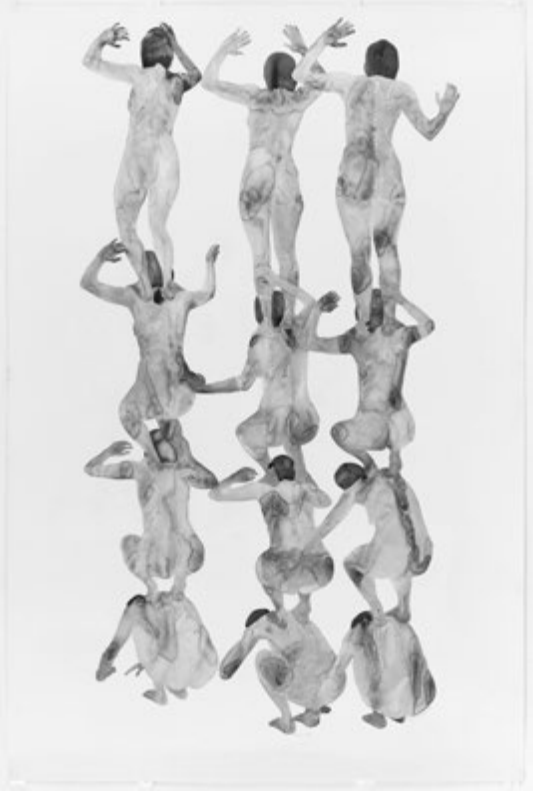
Journal of Medical Internet Research, Vol 20, No 6, (2018) June



BODYBUILDING I - CAREN van HERWAARDEN

Röntgenbril
Als kind wilde Caren van Herwaarden een röntgenbril om dwars door de kleren en de huid van anderen heen te kijken. Hoe ze zichzelf en anderen ervoer, kon ze maar moeilijk rijmen met de spieren, organen, botten en bloed waaruit we zijn opgebouwd. Het is een manier van kijken die Van Herwaarden nog steeds eigen is en in haar werk een grote rol speelt: hoe verhouden we ons als denkend wezen tot ons lichaam, tot deze zak met bloed, botten en slijm?

Anatomische collectie
Na de academie kreeg ze toegang tot de natuurhistorische en anatomische collecties van de Leidse Universiteit, en later tot de anatomische collecties van de universiteiten van Bologna en New Orleans. Van Herwaarden tekende daar het menselijk lichaam in talloze variaties van kracht, ontbinding en verval. Ze kon er letterlijk dóór de huid heen kijken. Dit intensieve onderzoek vormt de basis van haar werk. In deze oude collecties zie je terug dat kunst, religie en wetenschap ooit nauw met elkaar verweven waren. Het was bijzonder om te zien hoe men door de eeuwen heen met het menselijk lichaam omging, hoe men tegen leven, ziekte, afwijkingen of dood aankeek. En het vervolgens met wetenschap, kunst en religie probeerde te begrijpen en te bezweren. Deze fundamentele behoefte hebben alle culturen gemeen.

Over Bodybuilding
In de aquarel Bodybuilding I vormen een aantal vrouwen de schakels van een menselijk hekwerk. Aan de basis hurken zij, maar hoe hoger de toren wordt, hoe méér ze rechtop gaan staan. Het lijkt uiterst fragiel: als één van hen bezwijkt, stort het hele hekwerk in.
Ons verlangen om een nietig onderdeel te zijn van een geheel is ambivalent; je wilt wel maar ook weer niet. Je wilt opgaan in de menigte maar er niet in verdwijnen. Hoe komt het dat eigenheid zo angstig wordt verdedigd maar dat het tegelijkertijd troostend kan zijn om je een schakel te weten in een lange reeks: geen individu meer te zijn maar een vlek, zoals in de aquarel? De ervaring om een nietig onderdeel te zijn voelt als bijna verdwijnen, maar het verlangen naar deze ervaring is essentieel. Want je hoort als bewegend en ademend wezen bij een soort, en dat horen-bij geeft je bestaansrecht.
Hoef je niet te verdienen.

www.cvanherwaarden.nl

Foto: Peter Cox