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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.

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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. 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, Fig. 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 (Table 2). 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 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?

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

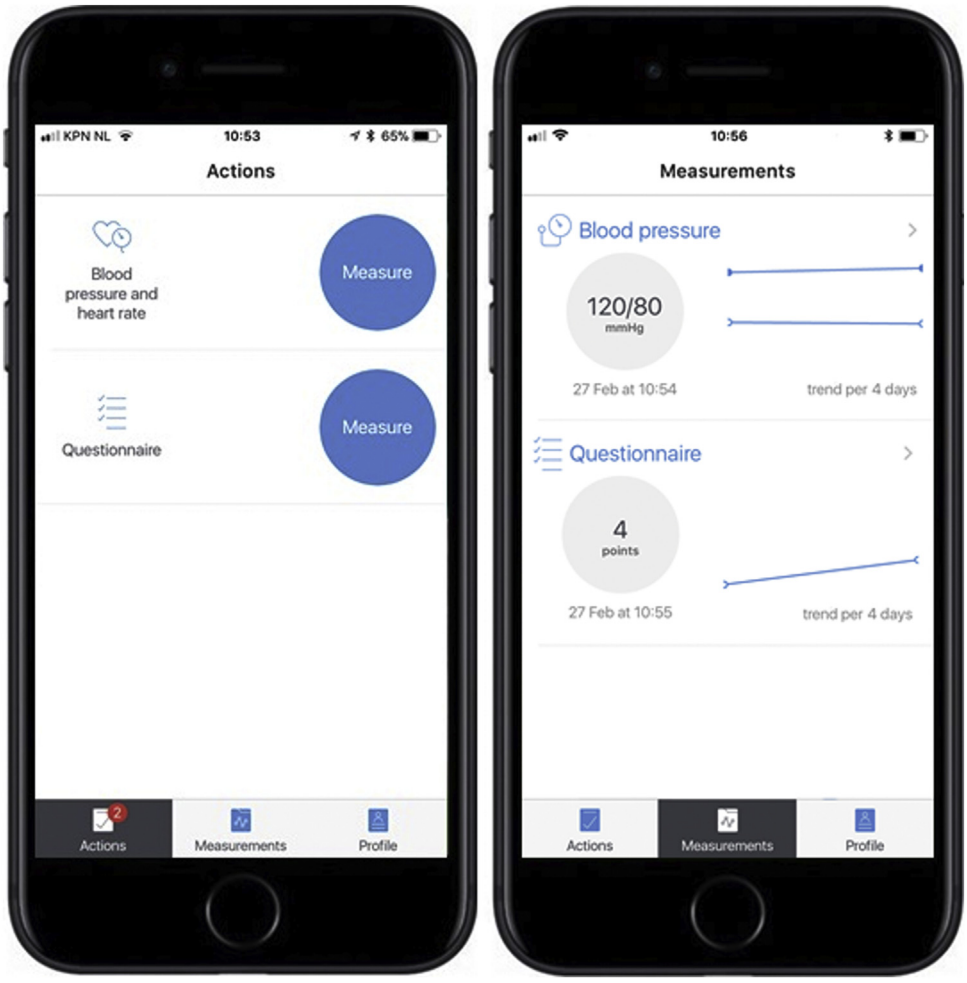

Fig. 1. Impressions of the Luscii cVitals app for use in prenatal care. Left: Actions screen of the app with 2 buttons to measure vital signs (using the Bluetooth connected monitor) and to fill out the symptom score list. Right: in the Measurements screen of the app participants can review their own data visualized in trend graphs.

Table 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	

Table 3
Maternal characteristics (total n = 14). *(BMI, body mass index).*

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)

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.

Participantinteraction 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 (see Fig. S1 for an example) 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 (Fig. S1). 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.

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 min a day (mean 3.4 min) 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

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

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 %

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

	Alarm type	n (%)	After manual check	Clinical impact
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	
Total BP submitted		**186**		

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) (Fig. S2). 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 favorable 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 min measurement activity did not interfere with daily activities. Participants reported favorable 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]. Enrollment 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 behavior 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 either 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 center, 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 plaform 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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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ejogrb.2019.07.012.

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