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The feasibility of multimodality remote monitoring of maternal physiology during pregnancy

Agata P. Zielinska, MB, BChir, BA, PhD[a], Edward Mullins, BMBS, PhD[a,b], Christoph Lees, MD, FRCOG[a,b,*]

Abstract

Gestational hypertension affects 10% of pregnancies, may occur without warning, and has wide-ranging effects on maternal, fetal, and infant health. Antenatal care largely relies on in-person appointments; hence, only <4% of the pregnancy period is subject to routine clinical monitoring. Home monitoring offers a unique opportunity to collect granular data and identify trends in maternal physiology that could predict pregnancy compromise. Our objective was to investigate the feasibility of remote multidomain monitoring of maternal cardiovascular health both in and after pregnancy.

This was a prospective feasibility study of continuous remote monitoring of multiple modalities indicative of cardiovascular health from the first trimester to 6 weeks postpartum.

Twenty-four pregnant women were asked to monitor body weight, heart rate, blood pressure, activity levels, and sleep patterns daily. Study participants took on average 4.3 (standard deviation [SD] = 2.20) home recordings of each modality per week across the 3 trimesters and 2.0 postpartum (SD = 2.41), out of a recommended maximum of 7. Participant retention was 58.3%. Wearing a smartwatch daily was reported as feasible (8.6/10, SD = 2.3) and data could be entered digitally with ease (7.7/10, SD = 2.4).

Remote digital monitoring of cardiovascular health is feasible for research purposes and hence potentially so for routine clinical care throughout and after pregnancy. Fifty-eight percent of women completed the study. Multiple modalities indicative of cardiovascular health can be measured in parallel, giving a global view that is representative of the whole pregnancy period in a way that current antenatal care is not.

Condensed abstract: To ascertain whether remote multimodality cardiovascular monitoring of health in pregnancy is feasible, 24 participants were asked to daily monitor body weight, heart rate, blood pressure, activity levels, and sleep patterns. Study participants took on average 4.3 (standard deviation = 2.20) home recordings of each modality per week across the 3 trimesters and 2.0 postpartum (standard deviation = 2.41), out of a recommended maximum of 7. Thus, remote monitoring indicative of cardiovascular health throughout and after pregnancy might be feasible for routine clinical care or within the context of a research study.

Abbreviations: BP = blood pressure, BSA = body surface area, BW = body weight, CI = cardiac index, CO = cardiac output, HR = heart rate, MAP = mean arterial pressure, PWV = peak wave velocity, SD = standard deviation, SV = stroke volume.

Keywords: blood pressure, physiology, pregnancy, prenatal care, remote monitoring

1. Introduction

Antenatal care aims to optimize maternal and fetal outcomes by providing timely screening, monitoring, and treatment.[1–3] Current medical practice delivers this largely at periodic face-to-face appointments measuring basic physiological parameters of the pregnant woman and estimating fetal size, based on a schedule that was devised in the early part of the 20th century. However, measurements taken during scheduled antenatal appointments may not be representative of the pregnancy as a whole[4–6] and many women default scheduled appointments. It is reported that 83% of women attend all scheduled antenatal appointments[7] and 4% to 6% of women in the United Kingdom first see a medical professional only after 13 weeks of gestation.[8]

In the United Kingdom, the National Institute for Health and Care Excellence schedule of antenatal care recommends between 7 and 10 routine appointments with a health care professional while pregnant.[9] Thus, out of 280 days of typical gestation, <4% are subject to some form of clinical monitoring. A more comprehensive

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

The authors have no conflicts of interest to disclose.

The authors have no competing interest.

[a] Department of Metabolism, Digestion and Reproduction, Imperial College London, London, United Kingdom, [b] Centre for Fetal Care, Queen Charlotte's and Chelsea Hospital, Imperial College Healthcare NHS Trust, London, United Kingdom.

**Correspondence: Christoph Lees, Centre for Fetal Care, Queen Charlotte's and Chelsea Hospital, Imperial College Healthcare NHS Trust, Du Cane Road, London W12 0HS, United Kingdom (e-mail: c.lees@imperial.ac.uk).*

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monitoring regimen could increase our understanding of the changes that occur during pregnancy both at individual and population levels. As a result, it may become possible to more reliably discern trajectories of change in physiological parameters indicative of a healthy norm or of pathology. At an individual level, a comprehensive set of readouts could enable early detection of deviations from a personal baseline that precedes maternal and/or fetal compromise and thus allow enhanced monitoring or timely intervention.

Importantly, cardiovascular parameters before, during, and after pregnancy do differ between healthy pregnancies and those affected by serious obstetric conditions, such as preeclampsia (PE), fetal growth restriction, or recurrent pregnancy loss.[10–22] It seems likely that there would be both research interest and clinical utility in measuring changes in cardiovascular indices throughout pregnancy at the level of an individual. Monitoring of maternal well-being could be complemented by home-based tracking of physical activity, sleep, weight, and surveying maternal mental health. With these measures in place, scheduled antenatal visits could instead be utilized to measure parameters associated with maternal, fetal, and perinatal outcomes that require more sophisticated monitoring devices.

Recent implementation of monitoring of daily fitness activity and health among the general population[23,24] and the enthusiasm with which this technology has been adopted across various groups raise a unique opportunity for reimagining antenatal care. By utilizing this approach, one could shift the paradigm of pregnancy care from opportunistic measurements in the clinical setting to continuous monitoring from the comfort of a woman's own home. The feasibility of such an approach for home blood pressure (BP) monitoring is established,[25] but for a wider panel of clinical parameters of interest for both clinical practice and research is currently unclear.

To establish the adherence to self-monitoring recommendations among a pregnant population and whether it changes across different stages of gestation and postpartum, we performed a prospective feasibility study in which women were asked to self-monitor health in pregnancy while receiving routine antenatal care supplemented with periodic noninvasive assessment of cardiovascular function. This package was designed to obtain a global view of women's health in pregnancy that is representative of the whole pregnancy and postpartum period. Here, we outline the study protocol, ascertain the feasibility of this approach, and aim to inform future sample size calculations for studies of uncomplicated and complicated pregnancies.

2. Methods

2.1. Design

This was a prospective feasibility study of recruitment, adherence to daily health monitoring, and participant satisfaction from first trimester to 6 weeks postpartum.

2.2. Participants

This feasibility study aimed to recruit 20 pregnant women who were willing to perform daily home monitoring of their bodily physiology, attend 4 clinic visits, and fill in study questionnaires at 3 predetermined intervals. Inclusion criteria were as follow: age 18 to 45 years, ≤12-week gestation at the time of enrollment, ability to provide informed consent and communicate in English, and being registered for maternity care at Queen Charlotte's and Chelsea Hospital, Imperial College Healthcare NHS Trust, London, United Kingdom. In order to gain a more comprehensive picture of physiological changes that may occur in pregnancy, study participants could be either nulliparous or multiparous, and high-risk pregnancies were not excluded. The exclusion criteria were as follow: unwilling to use electronic devices, lack of a smartphone compatible via Bluetooth with the smartwatch, and being on antihypertensive, antidiabetic, or antiepileptic medications.

Participants could leave the study at any time throughout study duration without providing an explicit reason. Additionally, the investigators could withdraw a participant from the study due to urgent medical reasons. Participants who dropped out from the study within 3 months of enrollment were replaced by new participants.

2.3. Recruitment

Study participants were recruited via advertisements in maternity clinics and social media. In brief, individuals who expressed interest and met the inclusion criteria were given an information leaflet during the first regular antenatal visit or a mutually agreed appointment. Individuals gave written, informed consent to enroll in the study. All individuals were given at least 24 hours between making the decision to enroll and initiating the study protocol.

2.4. Study protocol

The study protocol is outlined in Figure 1. During first visit, the participants were given written instructions and home monitoring devices, including a smartwatch, BP machine, and weighing scales (whose approximate combined value was £70). Participants were asked to continuously wear the smartwatch throughout pregnancy. A phone app provided by *Huma* (formerly *Medopad*) was downloaded by each participant to enter daily measurements of BP, hear rate, physical activity, weight, and sleep. The app provided all entered data to a portal, which was checked each day by the study team. Additionally, any hypertensive readings were acted upon by a follow-up in-person clinical assessment that day at Queen Charlotte's and Chelsea Hospital, Imperial College Healthcare NHS Trust, London, United Kingdom. In this way, the investigator had an opportunity to promptly act on any results that required medical attention.

Participant mental health and well-being were additionally overseen using paper questionnaires ascertaining depression, anxiety, and physical activity. This was done at 3 predefined intervals: point of enrollment, week 34, and around 6 weeks postpartum for the questionnaires. Additionally, noninvasive monitoring of cardiovascular function (not described further in this report) was performed by study clinicians during 4 in-person appointments: point of enrollment, week 20, week 34, and 6 weeks postpartum.

At the postpartum visit, the participants were asked to return the smartwatch, BP machine, and weighing scales. Additionally, a £70 voucher was given to each participant who returned the devices in a functional state.

Throughout the study, the investigators had access to participants' electronic medical records. This was in order to collect patient demographics and also obtain data on pregnancy outcomes and neonatal health.

Patient confidentiality was maintained for stored data throughout the study by allocating each participant to a unique ID code identifier, which was also linked to the phone app login. The master spreadsheet linking the unique ID code identifier with personal details was stored on an NHS Trust computer and protected by an encrypted password. This information was available only to the clinical team, and the company responsible for maintaining the phone app (*Huma* (formerly *Medopad*)) had no access to identifiable patient information. All information has been stored according to the guidelines issued by Imperial College London and Imperial College Healthcare NHS Trust Information Governance Department.

2.5. Daily weight and BP monitoring

Study participants were asked to perform daily monitoring of weight (in kg) and systolic/diastolic BP (in mm Hg)

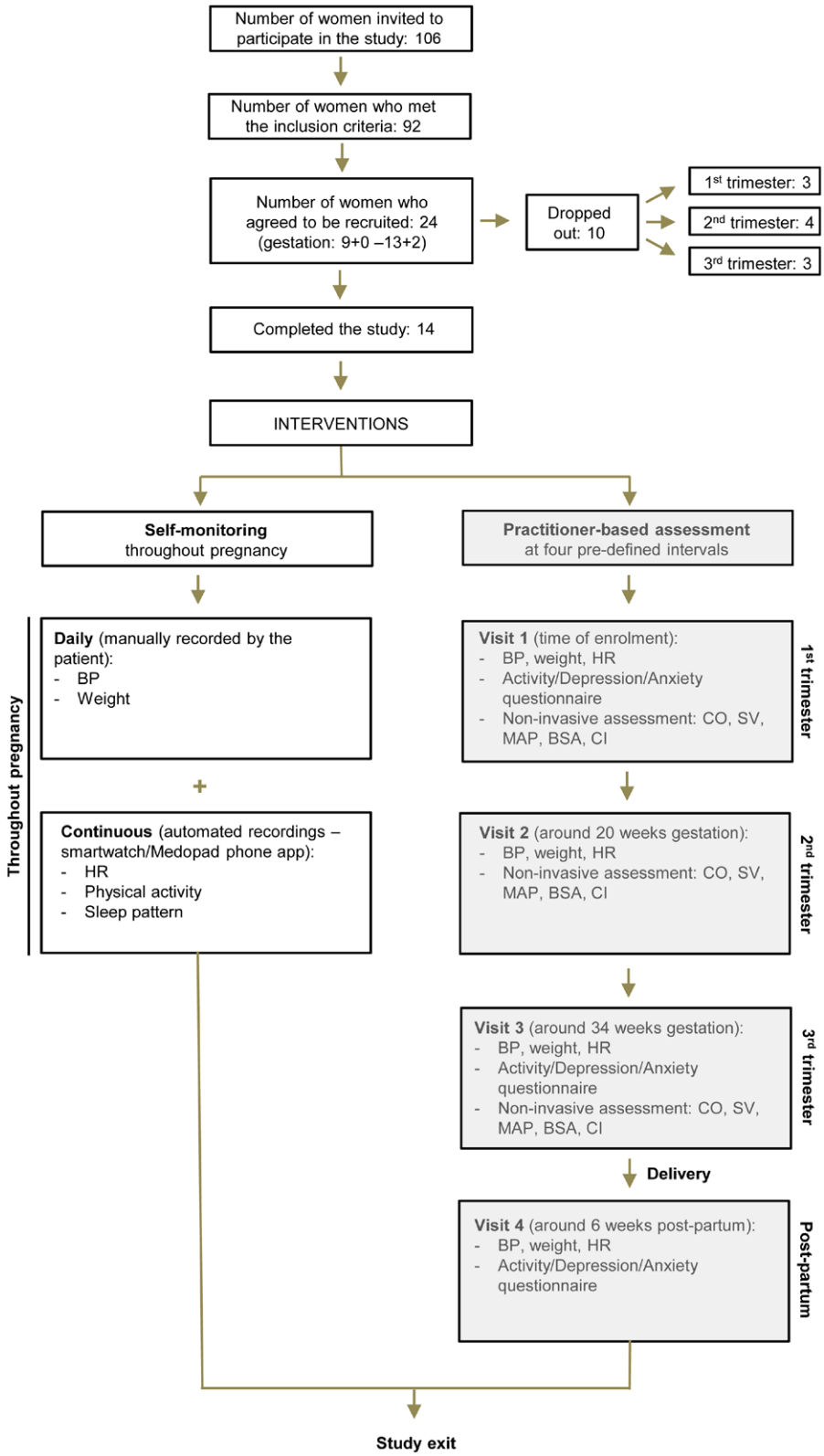

Figure 1. Study design flowchart. This article focuses on multimodality remote monitoring of pregnancy health, thus results collected during the in-person visits (highlighted in gray) are not described in detail in the current article. BP = blood pressure, BSA = body surface area, CI = cardiac index, CO = cardiac output, HR = heart rate, MAP = mean arterial pressure, SV = stroke volume.

using the devices provided by study organizers. The values recorded were then manually entered into the mobile app by study participants. The study team was monitoring the recordings with the view of contacting the participants if an abnormal result with potential clinical significance was detected. Additionally, participants were given written information on what constitutes an abnormal BP reading so that they were empowered to actively seek medical help if needed. Interestingly, only 4 of 1956 (0.2%) home systolic BP recordings exceeded 140 mm Hg.

2.6. Continuous monitoring using a smart watch

Study participants were also asked to continuously wear a smartwatch throughout the study duration. Parameters recorded by the smartwatch included the following: heart rate, activity, steps taken, time awake, time asleep, and light/deep/rapid eye movement sleep duration. These values were automatically saved on daily basis in the app when study participant opened the app on the phone.

The participants could review parameters entered both manually and automatically; however, they could not modify these nor enter data in retrospect (i.e., after a 24-hour period has elapsed following the designated data input timeframe).

2.7. Study devices

BP monitor (Microlife, BP A1 EASY): this device type was chosen as it is validated for pregnancy using a standardized international protocol (British Hypertension Society) and has a CE mark.

Weight scale (Tristar WG-2421): this device was chosen because of its affordability, a CE mark, and no contraindication for use in pregnancy. The scale has accuracy of ±0.1 kg.

Smartwatch (Fitbit Inspire, Fitbit): Fitbit watches have been validated in peer-reviewed publications, including the accuracy of heart rate measurements across different physical activity intensity levels.[26,27]

2.8. Noninvasive monitoring of cardiovascular parameters during clinic visits and study questionnaires

As part of the study protocol, the study team undertook noninvasive assessments of maternal cardiovascular function (BP, heart rate, body weight, cardiac output, stroke volume, peak wave velocity, cardiac index, augmentation index, body surface area, and mean arterial pressure) during 4 in-person appointments and collected data on mental health parameters using the following questionnaires: Physical Activity Scale, Generalized Activity Scale, and Edinburgh Postnatal Depression Scale. This article focuses on continuous remote monitoring, and hence, the results of these interventions are not described here.

Additionally, participants were encouraged to engage in an informal semistructured interview at the points of study entry and exit. The aim of these interviews was to ascertain the perception of home monitoring, the overall experience of the study, and whether they would have recommended enrollment in similar initiatives to other pregnant women.

2.9. Study outcomes

The primary outcome of this study was to determine feasibility (ease of recruitment, participant retention, number of measurements undertaken at home, adherence to continuous wearing of the smartwatch, participant satisfaction) of the use of home monitoring of health in pregnancy for future studies utilizing daily monitoring of physiological parameters in a larger cohort of women in order to ascertain the effectiveness of interventions to improve maternal health. This approach could also identify parameters that are early indicators of pregnancy complications.

2.10. Sample size

This was a feasibility study, therefore no formal power calculation was performed.

2.11. Statistical analysis

All statistical parameters (means, medians, interquartile ranges [IQRs], and standard deviations) and Pearson correlation coefficient were calculated in Origin Pro (*OriginLab,* Northampton, MA). All box plots show median (line), mean (small square), 5th, 95th (whiskers), 25th, and 75th percentiles. For first trimester analysis, 3 patients had to be excluded due to registering for the study only once first trimester was completed (n = 2) or during the transition period (n = 1).

2.12. Ethics

Research ethics approval was obtained from the London Fulham Regional Ethics Committee and Health Research Authority – IRAS ID 233138. Each participant of the study was deemed to have capacity to consent to participation and had given written consent.

3. Results

3.1. Recruitment and characteristics of study participants

Twenty-four women were recruited (Table 1) at 9+0 to 13+2 weeks of gestation, and for most study participants, this was the first or second pregnancy (nulliparous: 50%; parity IQR, 0–1). The median age was 32 (IQR, 28.5–37.5) and half of the participants were Caucasian. The median prepregnancy body mass index was 23.4 (IQR, 21.8–27.9).

Most women recruited were educated to a degree level (79.2%) and 91.7% were employed. Additionally, 91.7% reported cohabiting with a partner (Table 1, bottom panel).

When questioned about cardiovascular risk factors (Table 2), 95.8% of study participants reported no alcohol intake and 25% reported they had previously smoked. 62.5% reported no caffeine intake, with 20.8% of study participants drinking ≥2 cups of coffee a day. The median daily activity level was 190 minutes, although this varied greatly among the study cohort (105–337.5).

3.2. Previous familiarity with digital health monitoring

To ascertain the cohort's background, we asked about previous exposure to health monitoring using digital devices (Table 3). 37.5% of study participants reported owning a smartwatch and the same fraction admitted using digital apps to track own's health. Interestingly, 75% of study participants reported Internet and not family/friends/health care professionals as their main source of advice when health reassurance was needed.

3.3. Adherence to the study protocol

Of 24 individuals who enrolled in the study and gave informed consent, 14 completed the study (Fig. 1; dropout rate 41.7%). Individuals who dropped out did so across all 3 trimesters, with the main reason given being lack of time and pregnancy-related fatigue.

Table 1

Demographic details of the study population.

	Participants	
Characteristics	**All (n = 24)**	**Completed the study (n = 14)**
Age, yr	32 (28.5–37.5)	32 (27.0–38.0)
Caucasian	50%	64.3%
Height, m	163.3 (160.0–169.3)	164.5 (160.5–170.0)
Weight, kg	66.5 (58.0–74.5)	68.5 (61.0–72.5)
BMI, kg/m^2	23.4 (21.8–27.9)	24.5 (22.7–27.0)
University degree	79.2%	71.4%
Employed	91.7%	92.9%
Cohabiting	91.7%	85.7%
Parity	50% nulliparous	50% nulliparous

Baseline characteristics of all those who enrolled in the study (n = 24) and those who completed the study (n = 14).
BMI = body mass index.

Table 2

Cardiovascular risk factors in the study population.

Characteristics		Participants	
		All (n = 24)	Completed the study (n = 14)
Activity level, min/wk		190 (105–337.5)	235 (120–420)
Alcohol intake, U/wk	0	95.8%	92.9%
	1	0%	0%
	2	4.2%	7.1%
Coffee, cups/d	0	62.5%	57.1%
	1	16.7%	14.3%
	≥2	20.8%	28.6%
Current smoker		0%	0%
Previous smoking history	Never	75%	64.3%
	Light	20.8%	28.6%
	Moderate	4.2%	7.1%

Baseline cardiovascular risk factors among those who enrolled in the study (n = 24) and those who completed the study (n = 14).

Table 3

Previous exposure to digital health monitoring.

Characteristics	Participants	
	All (n = 24)	Completed the study (n = 14)
Tracks health using digital apps	37.5%	42.9%
Previously owned a smartwatch	37.5%	50.0%
Mainly resorts to the Internet for health reassurance	75.0%	71.4%

Familiarity of study participants with digital health monitoring prior to enrollment in the study.

Across the 14 individuals who completed the study, a total of 1965 BP recordings, 1997 weight measurements, 2096 daily activity values, and 1702 sleep pattern evaluations were registered. For instance, for BP recordings, this equates to an average of 4.63 recordings per week across the 3 trimesters (Fig. 2A; 4.78 recordings for first trimester (SD = 2.23), 4.41 for second trimester (SD = 2.37), 4.70 for third trimester (SD = 2.25), and 1.67 recording per week in the postpartum period (SD = 2.08). While compliance with daily recordings varied greatly across individuals, those who were most adherent to the study protocol did so regardless of the recording modality (Fig. 2B; Pearson coefficient for the correlation between the number of manual and automated recordings: $R = 0.979$).

3.4. Participant experience

Study participants reported high level of satisfaction with participation in the study (Fig. 3). Women reported that wearing a smartwatch throughout the day was not problematic (8.6/10, SD = 2.3; where 1 = very problematic and 10 = not problematic at all) and that the data could be entered digitally with ease (7.7/10, SD = 2.4). There was also a strong preference for recording the data digitally, rather than in writing (would prefer to use a paper notebook: 3.2/10, SD = 3.0). Interestingly, study participants scored the daily requirement to record parameters as 6.3/10 (SD = 1.8, where 1 = not convenient at all and 10 = very convenient). Exit questionnaires revealed that many individuals would have preferred to enter the manual parameters on a weekly/bi-weekly basis, whereas they would be happy to wear the smartwatch on a daily basis.

4. Discussion

Despite proven effectiveness in other health care settings,[28–30] remote monitoring has been rarely implemented in antenatal care.[31] Here, we demonstrate that remote monitoring of various modalities indicative of cardiovascular health throughout the whole pregnancy period might be feasible for routine clinical care, and certainly so within a research study. To our knowledge, this is the first study that aims to understand how various modalities indicative of cardiovascular health monitored remotely change throughout pregnancy and postdelivery. Women who completed the study took, throughout the duration of pregnancy, an average of 5 BP recordings per week out of 7 recommended in the study protocol, which provides a detailed picture of physiological changes that occur during pregnancy. This is in contrast to the 7 to 10 measurements throughout the whole pregnancy that would have been routinely obtained had the woman not been enrolled in the trial.[9] It is also >1.1 to 1.5 measurements per week recorded in a feasibility study that investigated engagement with remote monitoring devices in the United States.[32]

In women with hypertension during pregnancy, home BP monitoring has been shown to be feasible and reduce false-positive diagnoses of severe hypertension.[25] Our findings support recent studies, which indicated that it may be possible to successfully engage pregnant women in remote monitoring.[32–38] In contrast to most studies in this field,[39] we took a multimodality approach and also extended our analysis of multiple health parameters to the postpartum period. Regular monitoring from the comfort of woman's own home is perhaps of particular importance in the current coronavirus disease 2019 pandemic, when many women and health care systems necessarily limit the number of in-person visits to health care establishments and pregnant women are advised to shield where possible.[40]

It is important to note that our study population comprised largely of highly educated women cohabiting with partners, many of whom routinely used digital resources as the prime source of health reassurance, and even then only <60% completed the study. Nevertheless, as the study required measurements not just of BP but also of weight and heart rate, this represents a greater burden of data recording than previous studies. Whether a similar adherence will be seen in a more representative population remains to be determined. Further research into enhancing participation among groups that tend to less eagerly engage with antenatal care is needed. Perhaps unsurprisingly, lowest adherence to the study protocol was observed in the postpartum period (<2 recordings per week). The demands of caring for a newborn baby are likely to have precluded regular interaction with manual data entry into an app. An exit questionnaire completed by study participants identified means by which adherence in future studies could be increased. These include no need for manual data entry (e.g., by using Bluetooth-compatible devices that automatically relay the measured parameters into the app), less frequent recording of more static parameters, such as body

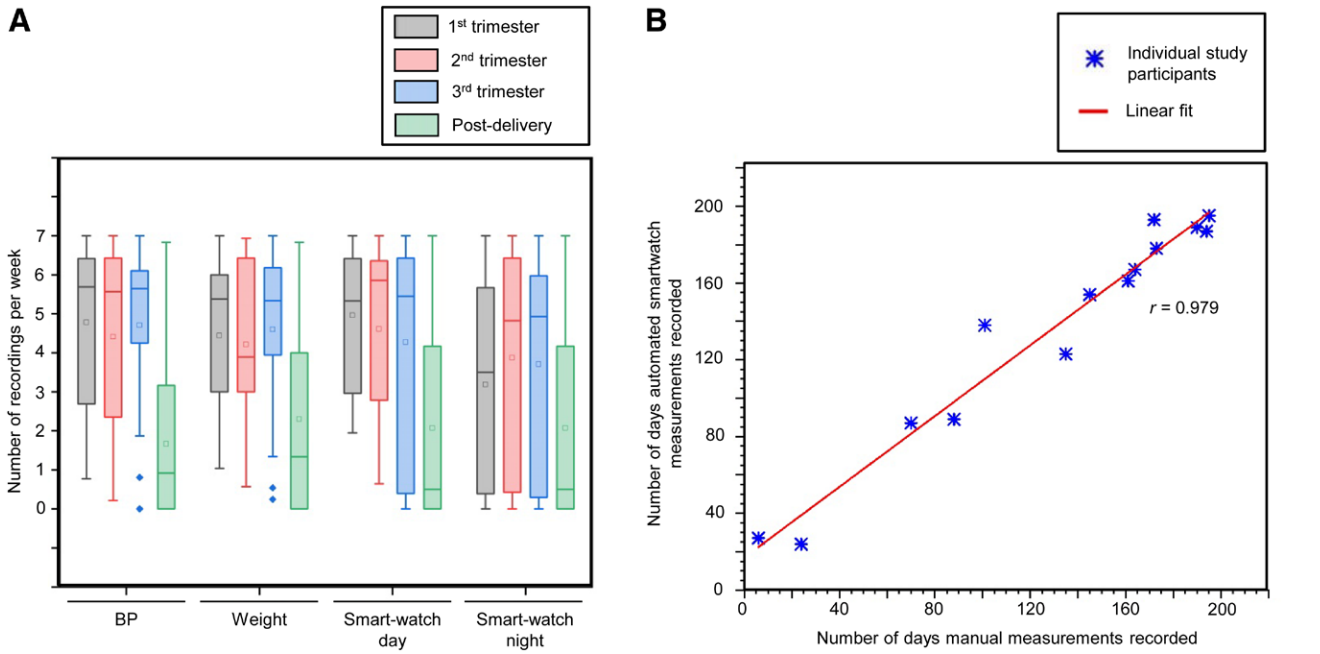

Figure 2. Remote multidomain monitoring can be used for a comprehensive monitoring of maternal physiology during and after pregnancy. (A) Box plots summarizing the number of recordings of each modality taken per week by study participants across different periods of pregnancy and postpartum. n = 14 study participants. (B) Relationship between number of days recordings were taken manually (blood pressure) and automatically (smartwatch) per study participant. Each asterisk represents 1 study participant. *R*, Pearson Correlation coefficient. n = 14 study participants.

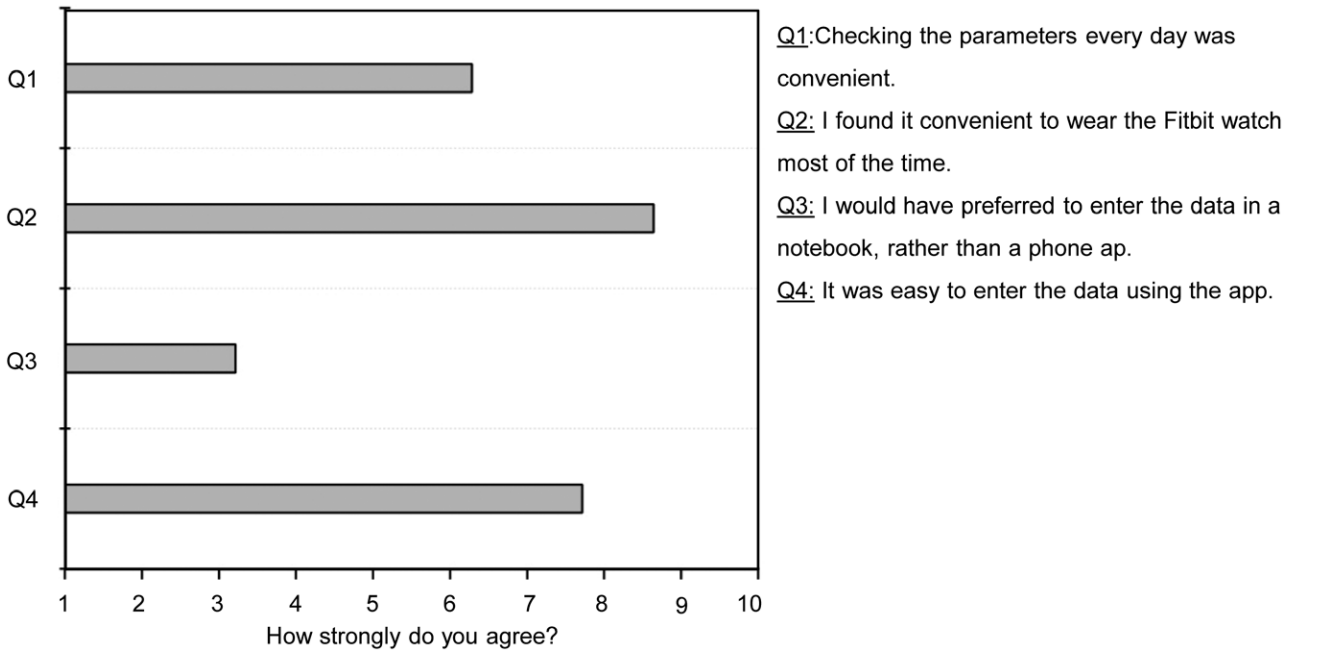

Figure 3. Results of the study exit questionnaire, which assessed participants' satisfaction. Responses were measured on a scale of 1 to 10, where 1 corresponds to "strongly disagree" and 10 to "strongly agree".

weight, and adapting the postdelivery protocol to less frequent observations postpartum. These suggestions are important, as they were raised by key stakeholders, the study participants themselves. Additionally, based on experience from other health care settings,[41] including digital aids to improve compliance with birth control methods, one could include within the app a daily reminder message to input the values.

Participant retention was 58.3%, which is lower than for other studies monitoring pregnancy health.[10,42] We would thus recommend, based on our findings, that twice the number of women are recruited as are required in a sample size calculation. This may be partially linked to the fact that the study was conducted during the coronavirus disease 2019 pandemic and some individuals had opted for minimizing contact with health care professionals during that period.[43–45] Alternatively, taking daily measurements using 3 different modalities may be too time-consuming during the busy period preceding delivery. Notably, daily monitoring may be better tailored to more specialized cohorts of pregnant women. Future studies in selected cohorts could identify characteristics of women who would benefit most from regular monitoring and are most likely to consistently engage with it.

There is strong evidence to suggest that the origins of PE are in cardiovascular dysfunction that may manifest itself early in pregnancy,[10,46] which underscores the rationale for these maternal measurements to be important in assessing risk of developing the condition and predisposition to it. Currently, management of serious obstetric conditions, such as PE or intrauterine fetal compromise, relies on risk prediction based on clinical and demographic parameters, increased surveillance in high-risk pregnancies, and if the condition manifests itself, then early delivery. While predisposition to PE may have some genetic contribution,[47] it is largely a disease of first pregnancy[48] that appears to have a strong cardiovascular component to its complex etiology.[10] Stratifying women accurately into low and high-risk categories preconception and in early pregnancy is challenging,[49,50] and the most accurate methods require additional clinical and laboratory resources for maternal blood testing.[51] Hypertension in pregnancy is associated with poor maternal and fetal outcomes and may denote the development of PE.[50] It is not difficult to make a coherent argument that daily monitoring of physiological parameters would detect early deviations from an individual's baseline and potentially aid early identification and safe management of this life-threatening condition, without the need for repeated visits to a health care facility.

Continuous monitoring of health in pregnancy among various women of different ethnicities, comorbid status, and parity can also increase understanding of pregnancy physiology. Increasing the number of measurements per pregnancy recently revealed that not all healthy pregnancies demonstrate a fall in BP in the first trimester.[52] Similar individual time- trends with regards to BP, heart rate, and other physiological parameters in pregnancy that may be associated with developing pathology offer the opportunity for targeted treatment and prevention.

This study demonstrates that continuous monitoring of health in pregnancy is feasible and could be modified to support future cohort and intervention studies of preconception, during and after pregnancy. This approach may be particularly valuable in women predisposed to cardiovascular disease or excessive gain weight, and hence bring us closer to personalized care of women who are to develop gestational hypertension and life-threatening conditions, such as PE. It is likely that these women are more motivated than healthy volunteers to undertake home monitoring. Of note, future large-scale studies will likely create enormous datasets if thousands of pregnant women record various cardiovascular parameters on a daily basis. Appropriate methods of data storage and statistical analysis will be required to exploit fully the information encoded and maximally benefit patient's care during pregnancy.

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Author contributions

A.P.Z. analyzed the data, prepared the figures, and wrote the article. E.M. designed the study and wrote the article. C.L. designed and supervised the study, and commented on the article.

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