

BMJ Open Ambulatory foetal ECG monitoring in low and high-risk pregnancies (AMBER2): a prospective cohort study protocol

Claire Pegorie ¹, Becky Liu ¹, Basky Thilaganathan ^{1,2}, Amarnath Bhide^{1,2}

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¹Fetal Medicine Unit, St. George's University Hospitals NHS Foundation Trust, London, UK

²Vascular Biology Research Centre, Molecular and Clinical Sciences Research Institute, St. George's University of London, London, UK

Correspondence to
Dr Amarnath Bhide;
abhide@sghul.ac.uk

ABSTRACT

Introduction Measuring foetal heart rate (FHR) is critical for assessing foetal well-being, and traditional cardiotocography (CTG), though effective, has limitations such as cost, accessibility and observer bias. Newer non-invasive foetal ECG (NIFECEG) devices offer more precise, reliable metrics for FHR variability and could enable remote monitoring, potentially improving early detection of foetal complications like hypoxia and stillbirth.

Methods and analysis This is a single-centre prospective cohort study taking place in a tertiary maternity unit in the UK. Women with a singleton pregnancy over 26⁺⁰ weeks will be approached for participation in the control, foetal growth restriction (FGR) or diabetic groups. The NIFECEG home monitoring schedule is 60 min daily for 7 days in the control group, daily from diagnosis until delivery for the FGR group, and daily from 36 weeks until delivery in the Insulin-dependent diabetic group. Longitudinal FHR raw ECG signals will be collected from participants across different gestational age ranges. Reference standards for FHR variability using metrics such as short-term variation, phase-rectified signal averaging acceleration and deceleration capacity will be established. The study will also aim to explore differences in FHR variability in FGR cases against controls and propose safety thresholds to guide decision-making for delivery.

Ethics and dissemination Approvals have been obtained from the London Stanmore Research Ethics Committee and from the Medicines and Healthcare Regulatory Agency. The results will be published in peer-reviewed journals, presented at conferences and used by the commercial sponsor to pursue European Conformity regulatory compliance marking and future clinical studies.

Trial registration number NCT06497205.

INTRODUCTION

Foetal heart rate (FHR) assessment is key for evaluating foetal well-being antenatally. Clinicians identify patterns in FHR suspicious of foetal hypoxia. Without intervention, this could cause cerebral palsy or stillbirth.¹ It is well recognised that FHR variability is the most important feature to indicate foetal hypoxaemia. Cardiotocography (CTG)—which uses Doppler ultrasound—is the gold

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This will be a prospective assessment of the feasibility and acceptability of home foetal heart rate (FHR) monitoring.
- ⇒ This study provides an opportunity to assess inter-foetal and intra-foetal variation in heart rate physiology.
- ⇒ This study will provide a large amount of baseline FHR ECG data from uncomplicated pregnancies, which can be used to construct reference standards.
- ⇒ This study focuses on home monitoring, which is not a controlled environment; therefore, it is vulnerable to incorrect placement, setup or use of the device.

standard for non-invasive FHR monitoring. This technology detects movement in the cardiac structures and from this approximates the FHR, requiring signal modulation and auto-correlation to provide accurate quality readings of FHR.² Traditional CTG analysis has several downsides. They are only available in hospitals with limited scope for remote monitoring, as the placement of the transducer needs to be done by healthcare providers, and self-application is not easily possible. Daily monitoring of pregnancies is impractical for both cost and logistical reasons.³ Most importantly, CTG interpretation is typically undertaken by visual inspection and is prone to considerable inter-observer and intra-observer variation.^{4 5}

Computerised CTG (cCTG) is a method developed to eliminate interpreter bias.⁶ It analyses FHR patterns and offers a computerised quantification of short-term variation (STV): an objective measure representative of the interplay between sympathetic and parasympathetic systems.⁷ A numerical assessment of STV cannot be discerned from visual inspection.⁸ Experience with cCTG shows that STV is the most clinically valuable parameter of foetal heart variability.⁹ A low STV has been associated with neonatal hypoxia

and stillbirth, and the use of cCTG has been shown to significantly reduce perinatal mortality.^{7 10 11} Early-onset FGR is most commonly caused by uteroplacental dysfunction, which is thought to be the most common cause of antepartum stillbirth in high-income countries.^{12–14} Experience from a randomised control trial of cCTG and Doppler ultrasound in severe preterm foetal growth restriction (FGR) demonstrated that close monitoring results in improved, neurologically intact perinatal survival.³ The minimum frequency of foetal monitoring in this study was twice weekly.¹⁵ Secondary analysis of the data showed that monitoring twice weekly may be too infrequent to predict deterioration of the foetal condition, and daily monitoring is probably needed.¹⁶ Indeed, integration of daily maternal, foetal and placental signal monitoring may be central to characterising gestational development and is likely to play a key role in stillbirth prevention.¹⁷

Foetal ECG obtained with electrodes placed on the maternal abdomen was first described in 1906, and the last 20 years have seen a surge in research around non-invasive foetal ECG (NIFECG).^{18 19} It appears to be a promising method for recording FHR and providing a wider range of more precise heart rate variability (HRV) metrics.

ECG-derived HRV can be divided into time, frequency domains and non-linear measures. Standard deviation of normal-to-normal inter-beat intervals (SDNN) and root mean square of successive differences between consecutive cardiac cycle durations (RMSSD) are examples of time-domain analyses which, look at HRV over 24 hours or 5 min respectively.^{20–23} Phase rectified signal averaging (PRSA) is a method that analyses the average acceleration capacity (AAC) and average deceleration capacity (ADC) of the heart and is resistant to noise. In adult medicine, ADC is thought to be more accurate than left ventricular ejection fraction in predicting mortality following a myocardial infarction.²⁴ In foetal medicine, AAC has been shown to indicate foetal state deterioration 24 hours prior to STV in severe early FGR.²⁵ This could be a more sensitive parameter to use in the detection of foetal distress in uteroplacental insufficiency.

The Femom device was developed by Biorhythm Pte and uses abdominal electrocardiogram as a basis for operation, it non-invasively captures both foetal and maternal ECG (fECG) signals from the maternal abdomen. Although other NIFECG devices are available, Femom is one of the few that women can self-apply to their abdomen without help from healthcare professionals (figure 1). Femom meets the FDA requirements for non-inferiority when

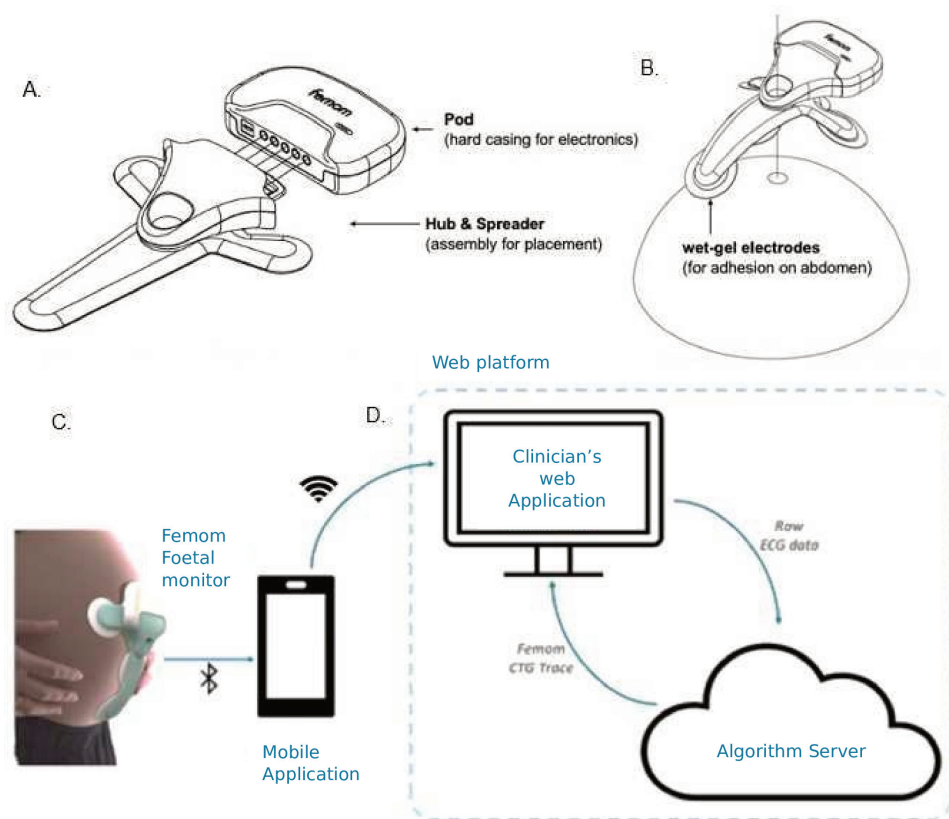


Figure 1 The Femom monitor. (A) The monitor consists of a pod and a spreader, which slot in easily. (B) Five electrodes (used for Holter ECG) are clipped onto the spreader, which is then placed on the maternal abdomen. The hole in the spreader is used to centre the spreader over the umbilicus for self-application. (C) The device is connected by Bluetooth to an Android phone with the Femom app preinstalled on it. The phone connects via wireless to the clinician's web application. (D) The clinician's web application sends the raw ECG data to a UK-based server. CTG, cardiotocography.

compared with a hospital CTG machine.⁸ Signal loss, although higher in NIFECG than cCTG, is less hindered by maternal and foetal characteristics (maternal body mass index (BMI), age, foetal position or foetal movements).²⁶ With appropriate filtering, STV obtained using the Femom and cCTG are highly correlated ($r=0.911$), with good Femom-cCTG correlations also obtained for AAC and ADC ($r=0.879$ and 0.895 , respectively).⁹ There is some evidence that PRSA may be superior to the traditional STV for the assessment of variability.²⁰

The principal objective of this study is to establish whether pregnant women can reliably obtain FHR recordings using Femom remotely without input from health-care professionals. Secondary objectives are to develop reference standards for FHR variability and PRSA indices. We aim to recruit women with pregnancies complicated by FGR and diabetes to compare FHR variability and PRSA indices to the established reference standards as a possible early marker of disease progression.

METHODS AND ANALYSIS

Recruitment and sampling

This is a single-centre prospective cohort study taking place at St. George's Hospital NHS Foundation Trust. Pregnant women attending the Antenatal Clinic, Day Assessment Unit or Foetal Medicine Unit will be approached for inclusion in the study. Once written and informed consent has been obtained (online supplemental material 1), they will be provided with a demonstration of the Femom kit and take this home to perform home foetal monitoring (figure 2 and detailed below). Delivery and neonatal outcome will be collected from their hospital records. Study recruitment will take place from April 2024 to April 2025. The expected end date for the collection of outcomes and data analysis is September 2025.

Sample size

As a proof-of-concept study, the sample size calculation is not based on powering for hypothesis testing. Rather, following Royston (1991, *SIM*),²⁷ it is based on establishing a reference interval such that the ratio of its width to the width of the 95% two-sided CI for the mean FHR at a particular gestational age in the range 26–40 weeks. This approach, suggested by Royston, assumes that the distribution of the FHR response is approximately normal with constant variance, that FHR variability is independent of gestational age. A sample size of around 130 independent observations will be needed to achieve this. Thus, FHR data from around 32 participants in each of the gestational week ranges: 26–30, 30–33, 33–37 and 37–42 will be collected. This will enable an even spread of participants over all eligible gestations.

The study aims to recruit 30–50 participants with pregnancies complicated by early onset FGR or insulin-dependent diabetes mellitus.

Inclusion and exclusion criteria

All women with a singleton pregnancy over 26⁺⁰ weeks' gestation who are over 18 years of age and can provide informed consent (have capacity, are able to speak English or have access to an interpreter) will be screened. The inclusion and exclusion criteria are detailed in table 1.

Study procedures and data collection

The Femom system provided to women in this study consists of the Femom foetal monitor and the Biorhythm research kit (figure 1). It includes a non-invasive foetal monitor, an Android phone, gel electrodes, a stencil with abrasive tape to prepare the skin and alcohol wipes to wipe their skin prior to the adhesive electrodes being placed on the abdomen. The monitoring schedule is a 60 min session once a day for 7 days in the control group, daily from diagnosis until birth for the FGR group, and daily from 36⁺⁰ weeks until birth in the diabetic group (figure 2). During the monitoring session, the participant will be blinded to the FHR and the ECG; all that is visible is a timer. The device does not contain ionising radiation and has been certified safe by the Federal Communications Commission in the USA. The standard Universal Mobile Telecommunications System cell phone transmits 33dbm (2W) of Bluetooth, while the low Bluetooth used on Femom will transmit at a maximum of 4dbm (2.5mW)—a fraction in comparison to a standard mobile phone. The electrodes are gel adhesive and similar to those used for Holter ECG electrodes. Patients will be asked whether they have had any previous allergies to electrode gel, and if so, they will be excluded from the study.

The device can be used remotely, where acquired foetal and maternal signals are transmitted via Bluetooth to a mobile phone. The mobile phone then transmits the data across Wi-Fi or mobile data to a server in the UK, which can analyse the signal and produce a computerised interpretation of the fECG signal (figure 1). The fECG trace will be acquired and displayed on the clinician's dashboard as a visual CTG trace, as well as having the signal loss and HRV metrics computed (figure 3). The trace will be available in approximately 2 min after submission by the participant. Trace acceptance will be determined according to signal loss during the monitoring session, as established by Liu *et al*.^{9 20 26} STV, PRSA, AAC and ADC will be computed according to the criteria established by Liu *et al* (figure 2).^{9 20 26} Other HRV metrics, such as SDNN, RMSSD and frequency, will also be obtained from the raw ECG data.

Data analysis

Outcome 1: assessing signal quality from monitoring and compliance

Maternal characteristics such as BMI, age, ethnicity, previous medical history and obstetric history will be recorded directly from the maternal medical notes. Signal loss will be reported as a percentage of the entire trace and will be compared and plotted in relation to

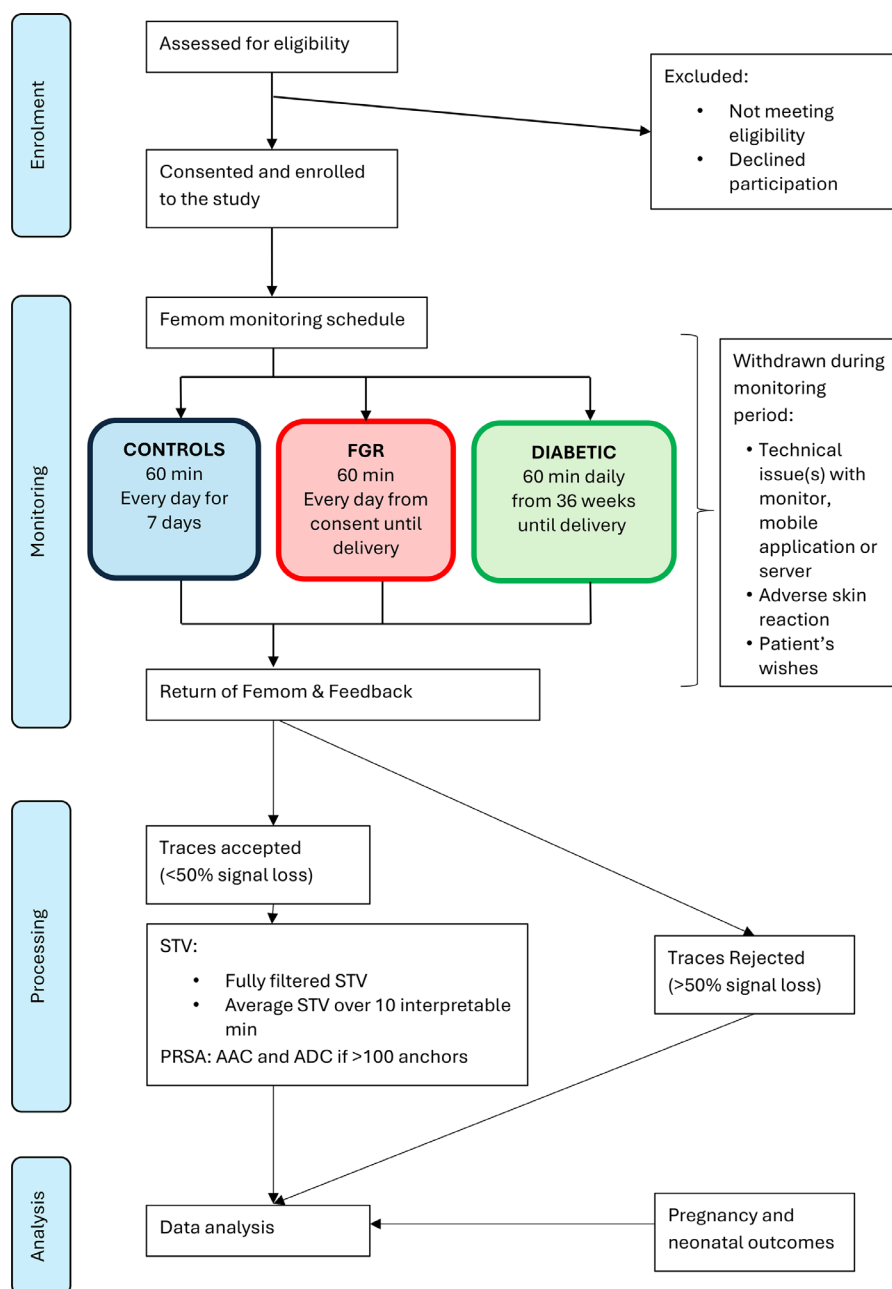


Figure 2 Study flowchart. AAC, averaged acceleration capacity; ADC, averaged deceleration capacity; FGR, foetal growth restriction; PRSA, phase rectified signal averaging; STV, short-term variation.

gestation. FHR parameters, including FHR, STV, PRSA, AAC and ADC, will be extracted from each Femom trace. However, it is important to note that no clinical decisions will be made based on this output, and the study will not have any impact on routine clinical care. The first endpoint is to determine the signal acquisition and interpretability of remote Femom monitoring. Multivariate logistic regression analysis will be employed to explore the impact of maternal characteristics (BMI, maternal age, medical history, smoking status, parity) and foetal characteristics (gestational age, small for gestational age (SGA)) on compliance, signal loss and FHR parameters (STV, AC, DC). Interpretability of the trace will be determined by the criteria set out in AMBER1 and are detailed

in figure 2. To assess the participants' compliance with the study protocol, the number of monitoring sessions completed according to the protocol will be measured. To meet the benchmark, participants should complete at least five out of seven monitoring sessions, with each session lasting a minimum of 40 min.

Outcome 2: compute reference standards for STV, PRSA, AAC and ADC in uncomplicated pregnancies according to gestation

The control group will be used to determine reference standards for normal pregnancy FHR parameters (STV and PRSA, AAC and ADC). Participants who develop pregnancy complications such as pre-eclampsia (PE), insulin-dependent gestational diabetes, low birth weight (below

Table 1 Inclusion and exclusion criteria for AMBER2

Inclusion criteria		Exclusion criteria
<ul style="list-style-type: none"> ▶ Singleton live pregnancy ▶ >26⁺⁰ weeks gestational age ▶ Able to speak English or available NHS interpreter 		<ul style="list-style-type: none"> ▶ <18 years of age ▶ Intellectual or mental impairment ▶ Known allergy or hypersensitivity to ECG gel electrodes ▶ Known foetal cardiac or genetic abnormality ▶ Existing dependent or unequal relationships with any member of the research team, the researcher and/or the person undertaking the recruitment/consent process ▶ Inability to access an interpreter
Control	Low risk ASPRE (Risk of pre-term pre-eclampsia <1/100) AND UtAd PI sum <2 at anomaly scan (20-22/40)	
FGR	Diagnosis of FGR according to the ISUOG definition: <ul style="list-style-type: none"> ▶ AC or EFW < 3rd centile OR ▶ AC or EFW < 10th centile and abnormal foetal or maternal dopplers 	
Diabetics	Diabetes requiring insulin	

AC, abdominal circumference; EFW, estimated foetal weight; FGR, foetal growth restriction; ISUOG, International Society of Ultrasound in Obstetrics and Gynaecology; NHS, National health Service; UtAd PI, Uterine Artery Doppler Pulsatility Index.

the 10th centile) or any significant pregnancy pathology will be excluded from this group. To calculate reference percentiles, a regression model will be constructed using FHR parameters (Baseline FHR, STV, AAC and ADC). These will be compared with published normograms where gestational age will be used as a continuous variable.^{23 28}

Outcome 3: explore deviations in FHR variability in FGR

FHR parameters in the FGR group will be plotted against the reference curves generated by the control group.

Descriptive statistics such as mean and SD for fECG FHR parameters will be reported as continuous data. St. George's Hospital follows the guidelines established by the Trial of Randomised Umbilical Flow in Europe (TRUFFLE study) to monitor and time delivery for pregnancies complicated with FGR. The Femom longitudinal data will be used to observe how far in advance of the delivery date the FHR parameters deviate from the established normal standards, and the relationship between these deviations and the clinical outcome of pregnancy.

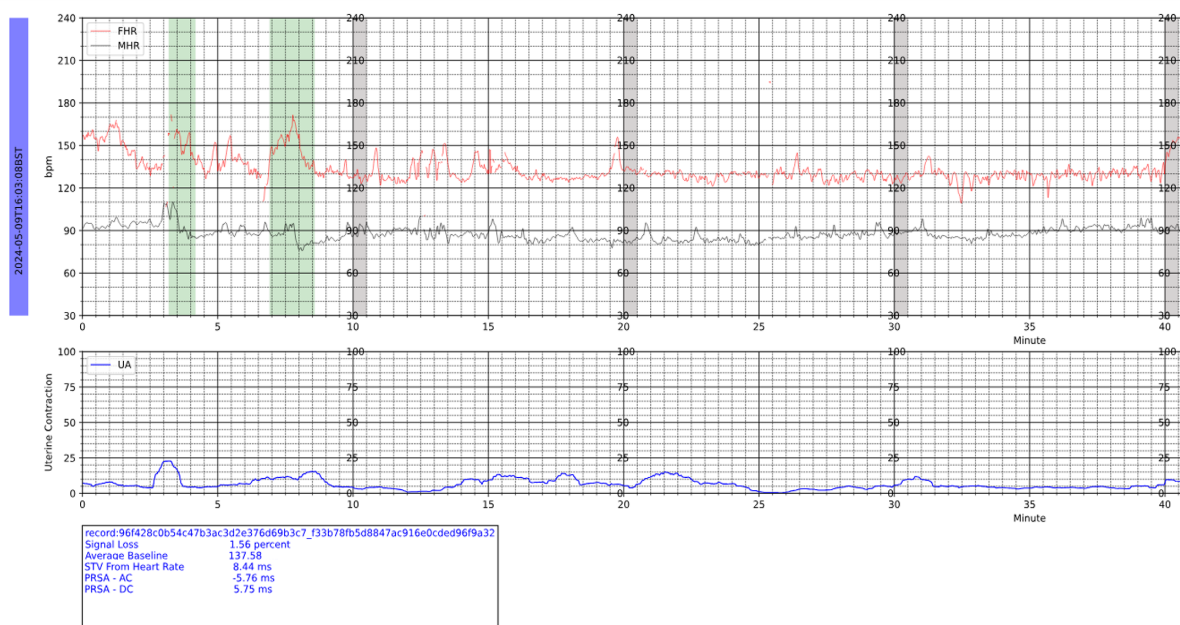


Figure 3 Clinicians' dashboard view. The monitoring session is dated and time-stamped. The non-invasive foetal ECG raw signals are processed and displayed as a cardiotocography trace. The red trace is the foetal heart rate (FHR). The black trace is the maternal heart rate. The blue trace is the uterine activity. The black box contains the blue indices of the FHR for this particular session. The top line is the record identification number. The signal loss is represented as a percentage of the whole trace. The average baseline FHR is in beats per minute (bpm). Short-term variation (STV) is calculated using FHR as per Dawes-Redman. Phase rectified signal averaging derived (PRSA), average acceleration capacity (AC) and deceleration capacity (DC) are also displayed.

Outcome 4: explore intra-foetal consistency for each FHR parameter

This is an opportunity to explore the intra-foetal consistency of each FHR parameter. Comparing intra-foetal consistency between foetuses can be done using a random slope model. Significant intra-foetal consistency will impact the interpretation of repeat traces obtained from the same foetus. An abnormally low STV in a foetus with consistently normal range STV may indicate a deterioration.

Outcome 5: establish the minimum time needed for valid FHR to be obtained by Femom and propose safety thresholds for STV and PRSA, AC and DC

The study also aims to establish the minimum time required by Femom to determine a reliable FHR. Survival analysis will be conducted to determine the number of consecutive beats and the minimum time needed to achieve this reliability.

The maternal and neonatal outcomes for each participant will be recorded from the routine medical notes. Any participants in the control group who develop PE or FGR subsequently will be excluded from the control group. Safety thresholds and real-time feedback will be proposed following this study to identify pregnancies at risk of adverse outcomes. Additional FHR parameters such as cardiac time intervals—namely QT interval, QTc, QRS complex duration and PR interval will aim to be derived from the foetal ECG signal. These metrics will be evaluated solely for the purpose of data collection.

Patient and public involvement and satisfaction questionnaires

Patient and public involvement (PPI) was not sought prior to commencing this pilot research protocol. All participants will be asked to provide feedback by completing a satisfaction questionnaire using a Likert scale. This will be done once they have completed their monitoring schedule. This will gauge patient satisfaction with the device and any areas that would need improvement. This will contribute to guiding future involvement of PPI, optimisation of the mobile application and development of the product.

ETHICS AND DISSEMINATION

This study has received ethical approval from the London Stanmore Research Ethics Committee (REC reference 23/LO/0744, IRAS ID 330204), and Medicines and Healthcare Regulatory Agency (Ref: CI/2023/0070/G), as well as Health Research Authority approvals. All participants will be given sufficient time to read the patient information sheet and sign the informed consent form. Monitoring will take place at home, and any adverse event will be reported directly to the study coordinator, who is responsible for reporting it to the sponsor. The severity of any adverse outcomes will be evaluated, and appropriate advice will be given to the participant. Adverse

events include ones those related directly to the use of the device, such as allergic skin reaction to the electrodes, or unrelated ones, such as vaginal bleeding or pain during the use of the device. Participants will be provided with the contact information of the study coordinator and research midwives if they would like to interrupt their participation in the study.

DISSEMINATION

The results of this study will be published in peer-reviewed journals and presented at national and international conferences. The commercial sponsors (Biorithm Pte) will proceed with CE marking of the device following dissemination of the results. Further studies will be set up and conducted based on our findings, prior to any approval for clinical use.

Contributors CP is the lead author of the protocol and a doctoral student in this study. BL has contributed to the conceptualisation, study design and protocol review. BT and AB are consultants in Obstetrics and Foetal Medicine, principal investigators of the study, and form the supervisory team for the doctoral student. They have both contributed to the conceptualisation, study design, statistical analysis and protocol review. AB is the guarantor. All authors have reviewed and approved the final version of the protocol.

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Competing interests CP is registered for an MD, which is funded by Biorithm Pte Ltd. BT is the Medical Director for Biorithm. AB is the Chief Investigator of a study funded by Biorithm Pte Ltd. BL has no current competing interests.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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ORCID iDs

Claire Pegorie <http://orcid.org/0009-0009-1286-415X>

Becky Liu <http://orcid.org/0000-0002-4968-8294>

Basky Thilaganathan <http://orcid.org/0000-0002-5531-4301>

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