**RESEARCH PROPOSAL-STUDY DESCRIPTION**

**Background**

Despite encouraging reductions, both maternal and infant mortality and morbidity remain unacceptably high. Globally, 830 women die from preventable causes related to pregnancy and childbirth every day and 2.6 million stillbirths occur around the world each year, especially in low-income groups. **Anemia and pre-eclampsia are the major factors of maternal ill-health**, and are implicated in prematurity, low birth weight, and stillbirth. **A quarter of the world’s neonatal deaths and 15% of maternal deaths occur in India.** **Hemorrhage and hypertensive disease/eclampsia are the major factors of maternal deaths in India,** and are implicated in low birth weight and stillbirth. Anemia has been associated with the risk of hemorrhage, and with a greater compromise after hemorrhage. For women living in remote areas, economic, infrastructure, gender and socio-cultural barriers limit attendance at formal antenatal care. In contrast, women’s groups practicing participatory learning and action have been shown to improve maternal and neonatal survival in low-income counties. However, these groups do not enable the consistent identification of specific complications in individual women.

WHO "Maternal Mortality" report (2016) stated that "*Every day, approximately 830 women die from preventable causes related to pregnancy and childbirth*". Of all the original Millennium Development Goals, the only one that is far behind the improvement curve is maternal mortality. As reported in Lancet Global Health (2016) although it is possible to diagnose pathological conditions, their treatment and resolution is not possible due to economic, cultural and customary conditions. However, women's groups practicing participatory learning and action are an effective approach to improve maternal and neonatal survival. In addition, based on new reports, heart rate variability (HRV), blood pressure variability (BPV) and oxygen saturation variability (OSV) are considered as among the most informative prognostic biomarkers. The ability to predict pre-eclampsia and anemia using the above-mentioned biomarkers could aid in the management, timely intervention, reduce morbidity and mortality and improve outcomes. Additionally, understanding and distinguishing pre-eclampsia from pregnancy-induced hypertension could facilitate treatment and prevention, reduce unnecessary iatrogenic intervention or inappropriate preterm delivery and avoid maternal morbidity.

An integrated solution to address key health factors of research and prevention, with the ability to improve health through knowledge of data collection, using an empathetic relational approach to promoting positive behavioural change, is necessary. This project will generate an integrated low cost, technical and socio-cultural solution that harnesses the socio-cultural acceptability of women's groups with wearable technology. The combination of the social and digital elements, using advanced data analytics and approaches to analyse the data, is intended to optimize the development of a broader understanding of healthy lifestyles and support decision making in treatments and interventions.

**The proposed approach is the first that combines a high-tech mobile monitoring system with the known social benefits of women’s groups, that can identify health status, promote personal behavioral change where needed, optimise acceptable referral where necessary, and map incidence and change in health status at a population level. The main goal is to reduce the incidence and adverse effects of anemia and hypertension in pregnant women, based on theories of technology adoption and of behavioral action**. In addition, by organising the measurements through local community groups it is possible to both reduce costs of care and enable 'mass' communications within the specific community.

Aim:

The aim of the current networking-feasibility study was to evaluate the potential advantages and capabilities of the use and integration of the proposed monitoring system into community groups of pregnant women in India. In addition, the aim of this feasibility study was to test the capability to collect data in real environment and to collect the views/feedback from clinicians and pregnant women from India, in order to design a solution that suits better their needs.

The objectives were:

1. To engage with community groups, pregnant women and clinical staff to define the technical specifications and other details that the software and the hardware need to contain based on local clinical needs and conditions.
2. To undertake data collection, management and analysis of personal health measures with groups of pregnant women (combination of analyses of digital data/vital signs and women's perceptions).
3. To co-operate with UK engineers for further data analysis, translation and algorithm development.
4. To establish the acceptability and feasibility of using the mobile monitoring system in combination with the known social benefits of women's groups.
   1. To assess pregnant women's views and the acceptability of the integrated monitoring system, using a simple questionnaire with 2 close-ended and 4 open-ended questions (data collection and analysis).
   2. To assess health professionals' and providers' views and the acceptability of the integrated monitoring system, using a simple questionnaire with 3 open questions (data collection and analysis).

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**STUDY CONDUCTED IN HYDERABAD INDIA**

**Methods**

The feasibility study was performed in two stages. At the first stage the UK team travelled to India to run the evaluation (details below). At the second stage the collected data were analysed in the UK and discussed between all project partners.

**Stage 1 (meeting in India):** The UK team will visited India [2 UCLan members (PI+1 Researcher)+ 1 Business partner (engineer)].

1. At this stage clinical staff, activists, midwives, consultants and other health professionals (defined as stakeholders) defined the technical and functional specifications of the proposed solution. For this purpose, relevant meetings were organised by the Indian partners with the UK team. During the meeting, the UK team presented the proposal and the monitoring system, and through an interactive discussion, the Indian partners involved in the project described the following:

a. Technical specifications of the software and hardware. What is needed in India and what would work better in relation to the monitoring system under discussion. Notes from this discussion recording the required needs were documented in the Appendix 1\_Notes from stakeholders meeting

b. Women’s groups: Appendix 2 were used to collect women’s view about the proposed solution. Please see Appendix 2\_Women's views survey.

*Notes for meetings with stakeholders:*

* *As no personal details were recorded and no other identifiers were able to be retrieved from the notes (Appendix 1), there was no need for a consent from the participants in these meetings. Prior to the beginning of each meeting, the participants were informed that words related to the above topics would be documented.*
* *All the participants in these meetings had to be literate in English, as all the discussion and explanation were performed in English language*

2. Data collection: Local researchers arranges and organised the measurements activities. The measurements activities took place either at the Fernandez Hospital and/or identified facilities by the Fernandez Hospital project group.

**Participants:** Before any data collection participants were informed in detail about the purpose of the study. Participants who were able to read and write either in English or in one of the local languages (Telugu, Hindi) were provided with an English or a translated version of the Participants Information Sheet. Participants who are not able to read and write in one of the above languages will be informed in detail about the purpose of the study by a local partner who will read to them the PIS and the consent form (Fernandez\_Hospital\_PIS\_Consent). Participants had the time and the chance to ask any question. Before any data collection, participants had to sign two copies of the consent form (one for them and one for the research team). For participants who were not able to write/sign or did not have any type of signature, a thump print were applied in the consent form (a stamp pad were provided).

Only participants who fulfilled the inclusion/exclusion criteria and agreed to participate in the study (and signed a consent form), enrolled the study. After the sign of the consent form only, the clinical staff/local researcher informed the UK researcher in which of the following groups the participant belonged: a) Healthy pregnant woman, b) Pregnant woman with pre-eclampsia, c) Pregnant woman with anaemia, d) Pregnant woman with pregnancy induced hypertension, e) Infection/Sepsis and f) Other/Information not know. This information were recorded by one of the UK researchers in the Participants Log Form (Appendix 4\_Participants Screening and Enrollment Log). Additionally, in the Participants Log Form participant’s age and the gestational age (in weeks) were recorded only if the participant knew this information and was willing to share it.

Inclusion criteria: Women who were pregnant and

* Could speak and/or read and understand one of the following languages: English, Telugu, Hindi.
* Were over the age of 18 and under (≤) 40
* Consent to take part
* Were available to attend the assessment session

Exclusion criteria: Women who

* Were not pregnant
* Can’t Can speak and/or read and understand one of the following languages: English, Telugu, Hindi.
* Were less than 18 years of age and over (>) 40
* Did not consent to take part
* Were not available to attend the assessment session
* Had chronic hypertension
* Had any significant disease or disorder which in the opinion of the investigator could either put the participant at risk or could influence the result of the study or the participant’s ability to participate in the study

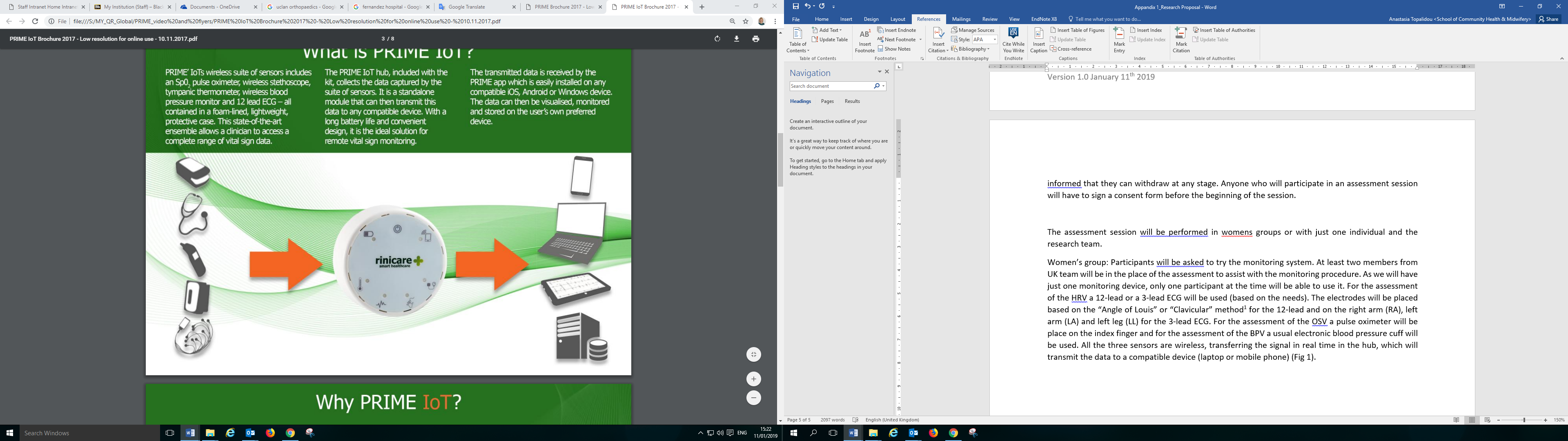
As this was a feasibility study we were not aiming to recruit a specific number of participants. To fulfil our objectives we intended to recruit at minimum 10 participants.

**Recruitment:** Women volunteers were recruited by the Fernandez Hospital. The world of mouth method were used for the recruitment.

**Assessment:** If any participant sign a consent form before the day of the assessment, she was reminded again of the protocol and was asked if she was still willing to participate. Participants were informed that they could withdraw at any stage. Anyone who participated in an assessment session had to sign a consent form before the beginning of the session.

The assessment session were performed in women’s groups or with just one individual and the research team.

Women’s group: Participants were asked to try the monitoring system. At least two members from UK team were in the place of the assessment to assist with the monitoring procedure. As we had just one monitoring device, only one participant at the time was able to use it. For the assessment of the Heart Rate Variability (HRV) a 3-lead ECG were used. The electrodes were placed based on the right arm (RA), left arm (LA) and left leg (LL) for the 3-lead ECG. For the assessment of the Oxygen Saturation Variability (OSV) a pulse oximeter were placed on the index finger and for the assessment of the Blood Pressure Variability (BPV) a usual electronic blood pressure cuff were used. Finally, for the assessment of women’s temperature, as usual digital thermometer were used. All the four sensors were wireless, transferring the signal in real time in the hub, which transmitted the data to a compatible device (laptop or mobile phone) (Fig 1). The transmitted data was received by the systems app, which gave the ability to visualise, monitor and store the data in real time.



**STUDY CONDUCTED IN BANGALORE - INDIA**

**Method**

Patient and public involvement (PPI) discussion to explore the acceptability of a mobile monitoring system to measure biomarkers in pregnancy. PPI work were conducted in partnership with a local NGO, the Bangalore Birth Network, who invited pregnant and postnatal women to participate in group discussions.

**Sample**

Pregnant and postnatal women. No specific number of women were required. Women were asked to agree to talk in a one-to-one or group discussion to explore their views about the mobile monitoring system. All participants had to be able to speak English, Kannada, Urdu/Hindi, Tamil or Telugu” (the local languages spoken in Bangalore).

**Mobile monitoring system**

The mobile monitoring system has an electronic blood pressure cuff, a pulse oximeter (placed on the index finger), and a 3 lead ECG (electrode placed on the right arm, left arm and left leg), and an electronic thermometer. Women were shown the monitoring system and given the opportunity to try on the sensors if they wish but we did not make any measurements.

**Data collection**

Members of the India team led the discussions and provide translation with women in one of the local languages specified. Women were asked open-ended questions to explore whether the system would be acceptable to them and what modifications if any would make the system more acceptable. The researchers made handwritten notes of the discussions.

No identifying data such as names or addresses were collected from participants, but we asked each woman her age, parity, and how many weeks pregnant (if applicable) to give us an overall demographic picture of the sample.

**Data reporting**

The findings of the discussions were summarised for research team use in designing an appropriate intervention that combines the mobile monitoring system with participatory women’s groups.

**ETHICS for study conducted in Hyderabad:**The study was approved by the “Institutional Ethics Committee – Fernandez Hospital” EC Rf. No. 29-2019 on the 21st of May 2019

The study was also approved by the University of Central Lancashire Ethics Committee (STEMH 1037 Amendment 3 June 2019)

**ETHICS for study conducted in Bangalore:**

The study was also approved by the University of Central Lancashire Ethics Committee (STEMH 1035 June 2019)

**Study conducted in two hospitals in Hyderabad – India**

**Files:  
1. Blank Copy of Participants Information Sheet and Consent form:** Document entitles “Fernandez Hospital\_PIS\_Consent”

**2. Blank copy of stakeholders meeting documentation**: Document entitled “Appendix 1\_Notes from stakeholders meeting”

**3. Plank copy of the participants log** “Appendix 4\_Participants Screening and Enrollment Log”  
Datasets:  
Qualitative 1:  
**1. Excel file entitled** “Responses to womens survey”: The Excel file contains responses from 13 women who participated in the study and used the monitoring system during their antenatal appointment.

**2. Word Document entitled “Appendix 2\_Women's views survey”** Is the survey that was used to collect participants views after they used the system during their antenatal appointment. The survey was translated in the all the local languages.

Qualitative 2:

**1. Word document entitled “Observations**” contains the observational notes from the visit to the two sites in Hyderabad.

**2. Stakeholders and Feedback Information meetings (word document):** Containing details based on the “Appendix 1 Notes from stakeholders meeting”

Quantitative 1:

**1. Participants log: Excel file containing the responses to the Appendix 4 log**

**2. RECORDINGS: Each file is named with the participant’s study ID that is logged in the Appendix 4. For each participants csv files with their exported biomarkers are included in the file.**

**Study conducted in a community setting - Bangalore**

**Files:  
1. Blank Copy of Participants Information Sheet and Consent form:** Document entitled “PIS CONSENT FORM BANGALORE”

**2. Blank copy of the discussion guide**: Document entitled “Appendix 1 v2 BBN Womens groups discussion guide”

**3. Blank copy of Basic Demographics** “Appendix 2\_Basic Demographics Log”  
**Datasets:  
Qualitative 1:**  
**1. Word document entitled** “Bangalore group”: Notes from discussion groups in community settings.