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WOMB: Wearable device to **O**bserve **M**ovements of your **B**aby (WOMB) study

Ethics Ref: 288119

Date and Version No: Version 1 18th November 2020

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Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host NHS Trust (s), regulatory authorities, and members of the Research Ethics Committee.

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1 AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made

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2 SYNOPSIS

Study Title	**WOMB: W**earable device to **O**bserve **M**ovements of your **B**aby (WOMB) study An observational study to investigate the effectiveness and acceptability of a wearable smart garment to independently detect foetal movements in pregnant women
Internal ref. no.	
Type of study	*Pre CE marking or Post Marketing Surveillance*
Trial Design	Observational study
Trial Participants	Pregnant women weeks 32-38 of pregnancy
Planned Sample Size	54
Follow-up duration	24 weeks
Planned Trial Period	June-December 2021
Primary Objective	To determine the effectiveness of the wearable device in detecting fetal movements, as identified by the operator scanning, compared with those detected by the pregnant women.
Secondary Objectives	1. To determine the positive-predictive value of the wearable device in detecting foetal movements, compared with the pregnant women. 2. To establish the acceptability of the device for women
Primary Endpoint	The proportion of movements, as identified by the scan operator, that are successfully detected by the wearable device and the pregnant women (i.e., their sensitivity rates), at weeks 32, 34, 36, and 38 of pregnancy.
Secondary Endpoints	1. The proportion of movements detected by the device and by the pregnant women that are true-positives, that is those that are also identified by the scan operator (i.e., their positive-predictive value rates), at weeks 32, 34, 36, and 38 of pregnancy. 2. Acceptability of wearing the device as self-reported by the women in a bespoke end of study questionnaire.
Device Name	WOMB version 1 device
Manufacturer Name	Kymira
Principle intended use	A garment that can be worn to monitor fetal movements

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3 ABBREVIATIONS

AE	Adverse event
ADE	Adverse Device Effect
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
CT	Clinical Trials
CTA	Clinical Trials Authorisation
EC	Ethics Committee (see REC)
GCP	Good Clinical Practice
GP	General Practitioner
ICF	Informed Consent Form
IEC	Independent Ethics Committee
IRB	Independent Review Board
NHS	National Health Service
NRES	National Research Ethics Service (previously known as COREC)
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SAE	Serious Adverse Event
SADE	Serious Adverse Device Effect
SIL	Subject Information Leaflet (see PIL)
SOP	Standard Operating Procedure
TMF	Trial Master File
UADE	Unanticipated Adverse Device Effect

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4 BACKGROUND AND RATIONALE

Fetal movements are reassuring for fetal health. It can be difficult for some woman to appreciate fetal movements and this can lead to unnecessary medical intervention.

We propose to test a thin, flexible textile-like sensor (which is conformable, breathable, and washable) embedded within a wearable garment, KYMIRA will create a solution that is easier and more comfortable for longer term monitoring. Moreover, the wearable will be fully washable, enabling better hygiene and potentially allow 24 hour monitoring.

We aim to correlate objectively measured fetal movements with those detected by the device via real-time imaging of the moving foetus using ultrasound.

We will be monitoring movements over a 20 mins period for women who are between 32-38 weeks of pregnancy. The device will monitor the movements, whilst a scan operator monitors movements and whilst the mother reports movements.

We aim to look at how fetal movements can be monitored in the third trimester using our device and check externally that the device works. We will scan a women 4 times in her pregnancy from 32-38 weeks whilst she is wearing the device. The device will need to be modified for the study so scanning can occur simultaneously.

Other studies have looked into various devices. Often these are bulky, non-washable and require hospital visits. Some use methods, such as picking up the acoustics of fetal movement (Lai J, 2018)). Our device works by using a piezoelectric fabric which essentially generates a tiny voltage when the material is bent or stretched. These studies have also looked at a 20-30min scan period and have shown this is sufficient time to notice movements (Melendez TD, 1992)).

5 OBJECTIVES

5.1 Primary Objective

To determine the effectiveness of the wearable device in detecting foetal movements, as identified by the operator scanning, compared with those detected by the pregnant women.

5.2 Secondary Objectives

1. To determine the positive-predictive value of the wearable device in detecting foetal movements, compared with the pregnant women.
2. To establish the acceptability of the device for women.

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TRIAL DESIGN

6.1 Summary of Trial Design

Prospective observational study. The scan operator will be blinded to the movements being detected by the device, and the device data will be processed by a separate independent person. It would involve four 20–30-minute visits. The first visit would include completing the consent and a 20 min scan. We would initially see the woman at around 32 weeks. Then 34, 36, 38 weeks and follow up at 6-8 weeks postnatal with a telephone call. A separate fabric element of the device will be made for each patient, in order to maintain the strictest of hygiene.

6.2 Primary and Secondary Endpoints/Outcome Measures

6.2.1 Primary Endpoints/Outcome Measures

The primary endpoint of the study is the proportion of movements, as identified by the scan operator, that are successfully detected by the wearable device and the pregnant women, at weeks 32, 34, 36, and 38 of pregnancy. These are the sensitivity rates of the device and pregnant women in detecting foetal movements, treating the scan operator detected movements as the “true” movements.

Fetal movement information noted on the scan would be collected by the operator pressing a foot pedal each time a movement is noted. If the movement persists, another event would be recorded. Fetal movements will be defined as any movement noted by the scan operator. Therefore, a combination of both trunk movements and limb movements will be recorded by the scan operator.

Maternal fetal movements noted would be collected by the mum pressing a button when she felt the movement.

The device will collect movements when the piezoelectric fabric is distorted by fetal movements. Maternal movements such as breathing and vessel pulsation will be filtrated out by software.

All three movements, device, maternally perceived and scan operator recorded will be recorded over 20 mins. The data will be time-stamped to allow matching of the movements, allowing for a degree of error (±500ms) to account for the reaction time of the mother and sonographer.

Raw voltage data collected by the device will be processed and converted to binary movements using an independent “training” subset of the data.

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Four separate scans will be undertaken 2 weeks apart. We would aim for these to be in 32nd, 34th, 36th, 38th week. With a margin of flexibility of one week.

6.2.2 Secondary Endpoints/Outcome Measures

The first secondary endpoint of the study is the proportion of movements detected by the device and by the pregnant women that are true-positives, that is those that are also identified by the scan operator, at weeks 32, 34, 36, and 38 of pregnancy. These are the positive predictive values of the device and the pregnant women, which will help understand the extent of false-positive movements and their impact on the usefulness of the wearable device.

The second secondary endpoint of the study is the acceptability of wearing the device as self-reported by the women in a bespoke end of study questionnaire. Please see Appendix 3.

6.3 Trial Participants

6.3.1 Overall Description of Trial Participants

Inclusion criteria are pregnant woman from 30 weeks of pregnancy. With no concerns raised regarding the pregnancy prior to this gestation and a body mass index (BMI) at booking of 18-30.

6.3.2

Inclusion Criteria

- Participant is willing and able to give informed consent for participation in the study.
- Female, aged 18-40 years.
- To start study prior to 32 weeks of pregnancy
- BMI 18-30 at booking
- Able (in the Investigators opinion) and willing to comply with all study requirements.
- Willing to allow her General Practitioner and Obstetric Consultant, to be notified of participation in the study.
- Singleton pregnancy

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Exclusion Criteria

- If any concerns have been raised at previous scans, although if the scan has been reviewed by fetal medicine and deemed there are no concerns then the patient can be included
- A delivery planned prior to 39 weeks at recruitment.
- Multiple pregnancy.

6.4Study Procedures

6.4.1 Informed Consent

The participant must personally sign and date the latest approved version of the informed consent form before any study specific procedures are performed.

Written and verbal versions of the participant information and Informed consent will be presented to the participants detailing no less than: the exact nature of the study; the implications and constraints of the protocol; the known side effects and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information, and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the informed consent. The person who obtained the consent must be suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participants. The original signed form will be retained at the study site.

6.4.2 Screening and Eligibility Assessment

Participants will be approached at 20 week scan, attendance at outpatient clinic or day assessment unit between 20-30 weeks. Then given a patient information leaflet and asked whether they would be happy to have a follow up phone call for screening and to see whether they would like to participate and be invited back for potential participation. The study will also be publicised within the Rosie and on the Rosie social media pages. Patients will also be able to contact the WOMB team to enquire about the study and enrolment.

Demographics

The date of birth, parity, gestation at first contact, estimated delivery date, body mass index at

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booking of pregnancy will be recorded.

Medical history

Plans to delivery prior to 39 week will be noted and the woman not eligible.

6.4.3 Baseline Assessments

Body mass index to be completed if not done at booking.

6.4.5 Subsequent assessments

The assessment of the patient will involve four twenty minute scans at 32,34,36 and 38 weeks. Where movements noted by mother, scan operator and device will be recorded separately. We would aim for these to be in 32nd, 34th, 36th, 38th week. For example, week 32 ±1 week, week 34 ±1 week, week 36 ±1 week, and week 38 ±1 week..The scans would take place ideally every 14 days but it would be acceptable with a 10-18 days gap. This allows for patient convenience. Summary of visits in Appendix 1.

6.5 Definition of End of Trial

The end of trial is the date of the last visit/ telephone follow up/ home visit of the last participant. The last phone call will occur at 8 weeks post natal.

6.6 Discontinuation/ Withdrawal of Participants from Study Treatment

Each participant has the right to withdraw study at any time. In addition, the investigator may discontinue a participant from the study at any time if the investigator considers it necessary for any reason including:

- Significant protocol deviation
- If the patient gives birth prior to the completion of the scan protocol. We will use the data from the scans up until that point and record they delivered prior to all scans being complete.
- Ineligibility (either arising during the study or retrospective having been overlooked at screening)
- Significant non-compliance with treatment regimen or study requirements
- An adverse event which requires discontinuation of the study or results in inability to continue to comply with study procedures
- Consent withdrawn
- Lost to follow up

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The reason for withdrawal will be recorded in the CRF.
If the participant is withdrawn due to an adverse event, the investigator will arrange for follow-up visits or telephone calls until the adverse event has resolved or stabilised.

6.7 Source Data

Medical records at Cambridge university hospital are on EPIC a computerised medial note system. These include, but are not limited to, hospital records (from which medical history and previous and concurrent medication may be summarised into the CRF).
All documents will be stored safely in confidential conditions. On all study-specific documents, other than the signed consent, the participant will be referred to by the study participant number/code, not by name.

7 TREATMENT OF TRIAL PARTICIPANTS

7.1 Description of Study Intervention(s)

The study intervention will involve four ultrasound scans lasting 20 mins during which fetal movements will be recorded. The fabric device will also be worn on the mother's abdomen and will also be recording movement. The mother will also have a button to press when she feels movements.

7.2 Maintenance and storage of device

The device will be in two parts. The fabric wearable part and a separate recording box with its own low power supply and data recording abilities. The fabric part will be new for each patient. The fabric part will be stored in a plastic sealed folder in the research room. Labelled with patients study number, in between scans. The plastic box part will be Clinicel wiped in between each patient. The device will be maintained by Kymira but training will be given to the staff at CUH.

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8 SAFETY REPORTING

8.1 Definitions

8.1.1 Adverse Event (AE):

An AE or adverse event is:

Any untoward medical occurrence in a patient or other clinical investigation participant taking part in a trial of a medical device, which does not necessarily have to have a causal relationship with the device under investigation.

An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of the device, whether or not considered related to the device.

8.1.2: Adverse Device Effect (ADE)

All untoward and unintended responses to the medical device.

The phrase "responses to a medical device" means that a causal relationship between the device under investigation and an AE is at least a reasonable possibility, i.e., the relationship cannot be ruled out.

All cases judged by either the reporting medically qualified professional or the sponsor as having a reasonable suspected causal relationship to the device qualifies as a device effect. For example, a rash at the site of contact with the fabric element of the device.

This also includes any event resulting from insufficiencies or inadequacies in the instruction for use or deployment of the device and includes any event that is a result of a user error.

8.1.3: Serious Adverse Event (SAE):

SAE is an adverse event that

- Led to death
- Led to fetal distress, fetal death or congenital abnormality or birth defect.
- Led to serious deterioration in the health of the subject that
    - Resulted in a life-threatening illness or injury
      NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it

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does not refer to an event which hypothetically might have caused death if it were more severe.

- Resulted in a permanent impairment of a body structure or a body function
- Required in-patient hospitalisation or prolongation of existing hospitalisation
- Resulted in medical or surgical intervention to prevent permanent impairment to a body structure or a body function
- Other important medical events*
  *Other events that may not result in death, are not life threatening, or do not require hospitalisation, may be considered a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the patient and may require medical or surgical intervention to prevent one of the outcomes listed above

To ensure no confusion or misunderstanding of the difference between the terms "serious" and "severe", which are not synonymous, the following note of clarification is provided:

The term "severe" is often used to describe the intensity (severity) of a specific event (as in mild, moderate, or severe myocardial infarction); the event itself, however, may be of relatively minor medical significance (such as severe headache). This is not the same as "serious," which is based on patient/event outcome or action criteria usually associated with events that pose a threat to a participant's life or functioning. Seriousness (not severity) serves as a guide for defining regulatory reporting obligations.

8.1.4: Serious Adverse Device Effects (SADE):

A serious adverse device effect (SADE) is any untoward medical occurrence seen in a patient that can be attributed wholly or partly to the device which resulted in any of the characteristics or led to a characteristics of a Serious adverse event.

SADE is also any event that may have led to these consequences if suitable action had not been taken or intervention had not been made or if circumstances has been less opportune.

All cases judged by either the reporting medically qualified professional or the sponsor.

8.1.5: Unanticipated Adverse Device Effect (UADE):

Any serious adverse device effect on health or safety or any life-threatening problem or death caused by, or associated with a device, if that effect, problem, or death was not previously identified in nature, severity or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated

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serious problem associated with a device that related to the rights, safety or welfare of the subject.

8.2 Reporting of AE

All AE's occurring during the study observed by the investigator or reported by the participant, whether or not attributed to the device under investigation will be recorded on the CRF as specified in the protocol. All ADE's will be recorded in the CRF.

The following information will be recorded: description, date of onset and end date, severity, assessment of relatedness to device, other suspect drug or device and action taken. Follow-up information should be provided as necessary.

The relationship of AEs to the device will be assessed by a medically qualified investigator or the sponsor/manufacturer and will be followed up until resolution or the event is considered stable.

All ADE that result in a participant's withdrawal from the study or are present at the end of the study, should be followed up until a satisfactory resolution occurs.

8.3 Reporting Procedures for All SAEs/ SADEs/ UADEs

All SAE/SADE/UADEs need to be reported to the sponsor/legal representative and manufacture and CUH R&D **immediately**; regardless of relationship to the device.

All reporting to CUH R&D should give as much information about the incident as possible, and should be signed by the PI or Co-investigator.

The CUH R&D Department will undertake an initial review of the information. Events will be followed up until resolution, any appropriate further information will be sent by the research team in a timely manner.

Reporting to the MHRA will be done in liaison with the Chief Investigator and the Manufacturer.

The Manufacturer has a legal obligation to report all events that need to be reported to the Nominated Competent Authority immediately (without any unjustifiable delay) after a link is established between the event and the device, but no more than:

- 2 days following the awareness of the event for Serious Public Health Threat.
- 10 days following awareness of the event for Death or unanticipated serious deterioration in health.

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- ♣ 30 days following the awareness of the event for all other event meeting the SAE criteria.

8.4: Annual Reports

In addition to the above reporting the Chief Investigator will submit once a year, throughout the trial, or on request a progress/safety report to the REC and R&D.

9 STATISTICS

9.1 Description of Statistical Methods/ Sample size

9.1.1 Analysis of Primary Endpoint

This is a pilot study to test KYMIRA's device on human subjects for the first time, with the primary outcome of interest being its effectiveness in detecting fetal movements, as identified by the operator scanning, compared with those detected by the pregnant women.

The analysis of the primary endpoint will therefore be a comparison of the proportion of movements, as identified by the scan operator, that are successfully detected by the wearable device compared with the proportion detected by the pregnant women, at each of weeks 32, 34, 36, and 38 of pregnancy separately.

The data to be analysed are the binary (Yes/No) outcomes for the device and the mother indicating whether each of the scan operator movements was successfully identified. There will be an outcome for the device and the mother (Yes/No, i.e., Detected/Not detected) for the same scan operator-identified movement. The data are therefore paired and a McNemar's test of paired proportions will be conducted to detect a difference in the proportions of movements detected by the device compared with the mother, if such a difference exists.

The same analysis will be repeated for the week 32, 34, 36 and 38 visit movements separately. The movements at a particular visit (either week 32, 34, 36 or 38) will be collated across the pregnant women for analysis. The repeated foetal movements for a given pregnant woman during a particular scan will be treated as independent.

9.1.1.1 Sample Size Determination

Previous studies that compared the number of fetal movements observed by ultrasound and those perceived by mothers during the 3rd trimester (Brown R, 2016) (Hertogs K, 1979) found the later to be highly varied; with different studies reporting different average fractions in the range of 0.16 to 0.44 (Hertogs K, 1979). Hence, we calculated the sample size for an

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assumed sensitivity rate of 44% for the pregnant mothers, corresponding with the most conservative estimate, i.e., to ensure adequate power. Based on the initial simulation tests of our device, we expect it to detect 0.8 to 0.9 fraction of the fetal movements. Allowing for a potentially lower detection rate in clinical practice, we assumed a sensitivity rate of 60% for the wearable device, again corresponding a larger sample size to ensure sufficient power.

For a single visit (week 32, 34, 36 or 38), based on a two-sided McNemar's test with a 5% significance level and 90% power, 395 movements are required (according to Lachenbruch (1992) (Lachenbruch, 1992)and based on the minimum estimate of the phi correlation r). Each pregnant woman is expected to have a minimum of around 10 foetal movements per 20 minute scan, as detected by the sonographer, therefore (rounding up) approximately 40 subjects are required for the study analysis.

In addition, an independent "training" subset of the data are required for calibrating the device. It is estimated that 3 subjects will be required for this purpose (i.e., approximately 30 movements), taking the number of subjects in the study to 43. Allowing for a drop-out rate of approximately 20%, a final sample size of 54 subjects (again rounding up) are estimated to be required for recruitment into the study. As the sample size required is based upon the number of foetal movements, if a different number of movements per mother is observed than assumed, the number of subjects recruited will be amended to ensure an appropriate total number of movements available for analysis.

9.1.2 Analysis of Secondary Endpoints

The analysis of the first secondary endpoint will be a comparison to the proportions of movements detected by the device and the pregnant women that are true-positives, i.e., those that are also identified by the scan operator, at each of weeks 32, 34, 36, and 38 of pregnancy separately. A z-test of independent proportions will be conducted to detect a difference in the positive predictive value rates for the device compared with the mother, if such a difference exists.

The same analysis will be repeated for the week 32, 34, 36 and 38 visit movements separately. Again, the movements at a particular visit (either week 32, 34, 36 or 38) will be collated across the pregnant women for analysis, and the repeated foetal movements for a given pregnant woman during a particular scan will be treated as independent.

For the second secondary analysis, frequency tables/summary statistics of the responses to the self-reported acceptability questions will be provided please see Appendix 3. The

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proportion of women agreeing that the device was acceptable to wear will also be reported, with corresponding 95% confidence interval.

9.1.3 Other Analyses

In addition to the analysis of the primary endpoint outlined above, an additional exploratory analysis may be conducted, pooling the data across visits and comparing the overall proportions of movements detected by the device compared with the mothers.

Summary statistics will be provided for subject demographics, medical history, and baseline measures.

9.7 Inclusion in Analysis

All data collected from scanning whilst wearing the data will be analysed. Even if the patient leaves the study prior to completing all 4 scans.

10 DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

Direct access will be granted to authorised representatives from the sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections. The electronic data collected by the device will be anonymised by the trial team, with no identifiable data other than the study participant number. Then sent electronically to the device team to analyse.

11 QUALITY CONTROL AND QUALITY ASSURANCE PROCEDURES

The study will be conducted in accordance with the current approved protocol, ICH GCP, relevant regulations and standard operating procedures.

Regular monitoring will be performed according to ICH GCP. Data will be evaluated for compliance with the protocol and accuracy in relation to source documents. Following written standard operating procedures, the monitors will verify that the clinical trial is conducted and data are generated, documented and reported in compliance with the protocol, GCP and the applicable regulatory requirements.

12 ETHICS

12.1 Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

12.2 ICH Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in full conformity with relevant

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regulations and with the ICH Guidelines for Good Clinical Practice (CPMP/ICH/135/95) July 1996.

12.3 Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), regulatory authorities (MHRA in the UK), and host institution(s) for written approval.
The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

12.4 Participant Confidentiality

The trial staff will ensure that the participants' anonymity is maintained. The participants will be identified only by initials and a participants ID number on the CRF and any electronic database. All documents will be stored securely and only accessible by trial staff and authorised personnel. The study will comply with the Data Protection Act 1998 which requires data to be anonymised as soon as it is practical to do so.

13 DATA HANDLING AND RECORD KEEPING

All study data will be entered on an excel file. Electronic data entry systems will be are validated and Standard Operating Procedures will be maintained.
The participants will be identified by a study specific participants number and/or code in any database. The name and any other identifying detail will NOT be included in any study data electronic file.

14 FINANCING AND INSURANCE

KYMIRA will provide funding for this study. The device under test is developed following IEC 62366, ISO 14971 and ISO 13485 for medical device safety, and IEC62304 for medical device software. Following and maintaining these standards is crucial as the proposed medical device product being developed will be classified under Class IIa as defined by the new medical device regulations (EU MDR 2017/745), and Class 2 under the USA's FDA 21 CFR Part 820.

15 PUBLICATION POLICY

The main report will be drafted by the CUH team with support from the Kymira team.

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Participants will be able to request trial results from their research team.

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16 REFERENCES

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Brown R, H. L. (2016). Maternal perception of fetal movements in late pregnancy is affected by type and duration of fetal movement. *The Journal of Maternal-Fetal and Neonatal Medicine*, 29:13, 2145-2150.

Hertogs K, R. A. (1979). Maternal perception of fetal motor activity. *Br Med J* , 2:1183–1185.

Lachenbruch. (1992). On the sample size for studies based upon McNemar's test. *Statistics in Medicine*, 11, 1521-1525.

Lai J, W. R. (2018). Performance of a wearable acoustic system for fetal movement discrimination . *PLoS ONE* , 13(5): e0195728.

Melendez TD, R. W. (1992). Characterisation of the fetal body movement recorded by hewlett packard M1350 fetal monitor. *Am J Obstet Gynaecol*, 167(3)700:2.

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17. APPENDIX

Appendix 1

Flowsheet of patient contact and journey throughout the study.

Appendix 2

Patient information Leaflet

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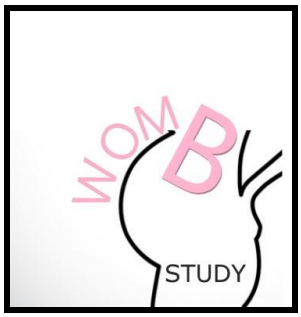
WOMB: **W**earable device to **O**bserve **M**ovements of your **B**aby (WOMB) study



Ethics Ref: 288119

Participant Information Leaflet

Introduction

You are invited to take part in a research trial. Before you decide, it is important that you understand why the research is being done and what it would involve for you.

Please take the time to read the following information carefully and take time to decide whether or not you wish to take part. You are welcome to ask us if there is anything that is not clear or if you would like more information. You might also want to talk to others about the study (for example your family, friends or your GP).

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In the rest of this leaflet Part 1 tells you the purpose of the trial and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the trial).

PART 1

What is the trial about?

Your babies movements are reassuring for their health. It can be difficult for some woman to appreciate their babies movements and this can lead to unnecessary medical intervention.

We are going to test whether a fabric we have developed can accurately pick up a babies movements. Hopefully this will allow us to create a solution that is easier and more comfortable for longer term monitoring of movement.

Can I take part in the trial?

You would be eligible to participate in the trial if you are pregnant with one baby.

Do I have to take part?

It is entirely up to you to decide. We will describe the study and go through this information sheet, which we will give you to keep. If you choose to participate, we will ask you to sign a consent form to confirm that you have agreed to take part. Your signature is not binding in any way and you will be free to withdraw at any time, without giving a reason. This will not affect you or your care in any way.

If your doctor believes that is in your best interest for you to stop participating in the trial, he or she will discuss this with you.

If any new information regarding your treatment becomes available during the course of the trial, your doctor will discuss this with you as well.

Whether you decide to participate in the trial or not, your decision will not affect your relationship with your doctor.

If you decide not to participate in the trial, you will receive the usual standard of care for your pregnancy.

What will happen to me if I take part?

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If you are eligible for the trial and you wish to take part you will first be registered onto the trial. This means you will be asked to provide written informed consent to confirm you wish participate in the trial.

We will ask you to come in for four extra 20 minute scans. During this scan you will be given a button to press when you feel the baby move. The scan operator will also press a foot pedal when they see the baby move. Then after the scan a different independent person will see whether the fabric has picked up the movements that both the mum and person scanning have noticed.

The reason we ask you to come for four scans is so we can see if the fabric works throughout the last 2 months of pregnancy.

8 weeks after the last scan we would telephone you to ask how your pregnancy went and what you thought of the product.

What are the possible disadvantages, side effects, risks and/or discomforts of taking part in this study?

The disadvantage of taking part in the trial is that we would ask you to come in to the hospital for four extra scans between 32 and 38 weeks of pregnancy.

What are the possible benefits of taking part in this study?

Taking part in the trial is not going to be directly beneficial to you personally, although you will get to see your baby on scan a few extra times.

Expenses and payments

Travel expenses up to £30 will be made for participation in this study.

What will happen when the trial ends?

The trial concludes 8 weeks after your last scan and, once you are discharged from hospital care, your GP will continue with your care as normal.

When the last participant has completed the trial, the information we have gathered will be analysed so that we can work out whether our device works to monitor fetal movements.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to your study doctor or nurse who will do their best to answer your questions (see the end of this leaflet for contact details).

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If you remain unhappy and wish to complain formally, you can do this through the Patient Advice and Liaison Service (PALS). Their full contact details are given in Part 2 of this leaflet.

Advertising poster

social media/

Consent

Protocol

Questionnaire

CRF

Instructions for use of device

Photos of the device

This concludes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

Who is organising and funding the trial?

This trial is funded by Kymira with a grant from Innovate UK.

Kymira is sponsoring the trial and covering the standard insurance and indemnity costs applicable to research trials.

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What will happen if I don't want to carry on being part of the study?

Participation in this study is entirely voluntary. If you decide you do not wish to participate in this trial it will not affect you in any way. If you decide to take part in the study, you will need to sign a consent form, which states that you have agreed to participate. However, you may withdraw from the study at any time without giving a reason and without it affecting you in any way.

You have the right to withdraw from the study completely and decline any further contact by study staff after you withdraw.

Your normal care will not be affected in any way.

Who should I contact if I wish to make a complaint?

If you have a concern or complaint about the Trial which has not been addressed by the study team, you can complain formally through the Patient Advice and Liaison Service (PALS):

Patient Advice and Liaison Service

Email pals@addenbrookes.nhs.uk

Telephone 01223 216756

PALS and Complaints Department,

Box 53,

Cambridge University Hospitals NHS Foundation Trust,

Hills Road,

Cambridge,

CB2 0QQ

Will my taking part be kept confidential?

Once you have agreed to participate, information about you is sent to the WOMB Trial Office which will refer to you only by a unique trial number and your initials so that you cannot be recognised. All information collected about you for this trial is strictly confidential. The information will be securely stored at the WOMB Trial office under the provisions of the 1998 Data Protection Act, and will be accessible only to authorised personnel from the WOMB team.

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Occasionally, we may need to access your medical records in order to check that the information provided about you is accurate. This will be done by clinical staff or designated personnel from the Trial Office.

Government regulatory agencies may also require access to your medical records to ensure that the trial is being run in accordance with UK law.

Only the local investigator at your hospital will have access to your personal details and can trace your identity. It will not be available to the team at KYMIRA. Data collected for the trial will be stored for up to 10 years after the end of the trial, as required by UK legislation.

What will happen to the results of the trial?

Once the study is complete the results will be published and a final report will be written. You will not be identified in any reports or publications and none of the data could be traceable to you personally.

What if I want any more information about the study?

If you have any questions about any aspect of the study, or your participation in it which has not been answered by this participant information leaflet, then please contact:

Fetal Medicine department

01223 217660

Suzanna.dunkerton@addenbrookes.nhs.uk

Dr Suzi Dunkerton

Thank you for taking the time to read this Participant Information Leaflet.

NHS
National Institute for Health Research

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Appendix 3

Questionnaire on the patient experience of the device.