REACH - WP3 'PREGNANCY CIRCLES' TRIAL

Protocol

PROTOCOL V. 4.0; 28/01/2020

IRAS number 228894

Full Title	An individual-level randomised controlled trial of group antenatal care
Short Title/Acronym	REACH Pregnancy Circles Trial
Sponsor	*University of East London* *Contact person of the above sponsor organisations is:* Dr Kenneth Gannon, Clinical Research Director, School of Psychology, University of East London Stratford Campus London E15 4LZ
Funding	NIHR-funded Programme Grant for Applied Research **RP-PG-1211-20015**
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1. GLOSSARY of Terms and Abbreviations

AE	Adverse Event
AR	Adverse Reaction
ASR	Annual Safety Report
CA	Competent Authority
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
DMC	Data Monitoring Committee
EC	European Commission
GAfREC	Governance Arrangements for NHS Research Ethics Committees
GROW	Gestation Related Optimal Weight
ICF	Informed Consent Form
JRMO	Joint Research Management Office
NPEU	National Perinatal Epidemiology Unit
NHS REC	National Health Service Research Ethics Committee
NHS R&D	National Health Service Research & Development
Participant	An individual who takes part in a clinical trial
PCTU	Pragmatic Clinical Trials Unit
PI	Principal Investigator
PIL	Participant Information Leaflet
PPI	Patient and Public Involvement
QA	Quality Assurance
QC	Quality Control
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SDV	Source Document Verification
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
TMG	Trial Management Group
TSC	Trial Steering Committee

2. SIGNATURE PAGE

Chief Investigator Agreement

The clinical study as detailed within this research protocol or any subsequent amendments will be conducted in accordance with the Research Governance Framework for Health & Social Care (2005), the World Medical Association Declaration of Helsinki (1996) and the current applicable regulatory requirements and any subsequent amendments of the appropriate regulations.

Chief Investigator Name: Professor Angela Harden

Chief Investigator Site: University of East London

Signature and Date:  **DATE 28/01/20**

Statistician Agreement

The clinical study as detailed within this research protocol **(**Version 4.0; 28/01/2020**)**, or any subsequent amendments will be conducted in accordance with the Research Governance Framework for Health & Social Care (2005), the World Medical Association Declaration of Helsinki (1996) and the current applicable regulatory requirements and any subsequent amendments of the appropriate regulations.

Statistician Name: Sandra Eldridge

Organisation: Pragmatic Clinical Trials Unit (PCTU), Queen Marys University of London.

Signature and Date: **DATE 28/01/20**

3. SUMMARY/ SYNOPSIS

Short Title	REACH Pregnancy Circles Trial
Methodology	Individual level randomised controlled trial with integrated process and economic evaluations
Research Sites	Barts Health NHS Trust, Whittington Hospital NHS Trust, Lewisham & Greenwich NHS Trust, West Hertfordshire NHS Trust, East Suffolk and North Essex NHS Foundation Trust, Princess Alexandra Hospital NHS Trust, Worcestershire Acute Hospitals NHS Trust, Basildon and Thurrock University Hospitals NHS Foundation Trust, Ashford and St Peter's Hospitals NHS Foundation, Royal Free London NHS Foundation, East Sussex Healthcare NHS Trust
Objectives/Aims	To determine the effectiveness and cost-effectiveness of group antenatal care in NHS settings serving populations with high levels of social deprivation and cultural, linguistic and ethnic diversity.
Number of Participants/Patients	1732 pregnant women will be recruited to the trial – 866 will be randomised to receive group antenatal care and 866 to receive standard antenatal care
Main Inclusion Criteria	Women who are currently pregnant and registered for antenatal care with the included NHS Trust maternity services, whose estimated due dates fit with the proposed group start dates, and who live within the usual working areas of these services.
Statistical Methodology and Analysis (if applicable)	Analysis on intention-to-treat basis of participant outcome data using mixed effects regression models (logistic random intercept model for primary outcome) accounting for within Pregnancy Circle correlation in the intervention arm.
Proposed Start Date	01/09/2018
Proposed End Date	12/10/2021
Study Duration	37.5 months

4. INTRODUCTION

Study overview

This study is part of a NIHR-funded Programme Grant for Applied Research (PGfAR), the REACH[1] Pregnancy Programme (Reference RP-DG-1108-10049), which aims to improve women's access to, engagement with, and experience of antenatal care. The Programme comprises four main components:

1. A community engagement intervention to increase early uptake of antenatal care. (Work Package 1)
2. A two-stage feasibility study to develop and test a bespoke model of group antenatal care (called Pregnancy Circles) followed by a pilot trial (Work Package 2).
3. **A full randomized controlled trial of group antenatal care (Work Package 3) (This study)**
4. Strengthening the efficacy of user representation in maternity services (Work Package 4).

This protocol describes the trial of a bespoke model of group antenatal care called Pregnancy Circles. The trial aims to assess the effectiveness of this type of care, compared with standard antenatal care, in improving women's experiences of care and for improving maternal and newborn health outcomes in an NHS-setting serving populations with high levels of social deprivation and cultural, linguistic and ethnic diversity. Pregnancy Circles involve the organisation of care for about eight to twelve women in a group, where the women are all due to have their babies around the same time. The Pregnancy Circles are facilitated by two midwives. The model of care integrates clinical care (standard antenatal checks such as blood pressure and urine testing) with information sharing and the opportunity for peer support. Care is organized in this way for the women throughout their pregnancy and replaces standard midwifery antenatal appointments. Each Pregnancy Circle meets for two hours in contrast to the usual around 15 to 30-minute standard antenatal appointment. There is some robust evidence from other countries that compared to conventional care, antenatal care provided within this type of group model has a positive impact on women's experiences of antenatal services by providing women-led care, better continuity of care, easier and more comprehensive (and possibly more effective) sharing of information and enhanced opportunities for social support. There is also evidence indicating improvements in pregnant women's engagement with services and birthing outcomes, such as reduced rates of preterm birth and low birth weight in babies, and improved breastfeeding practices. Furthermore, evidence of positive effects on midwife facilitators' job satisfaction, and other organisational outcomes has been found. A significant opportunity to improve women's access to services is also provided with this model, where we are aiming to provide more antenatal care in community settings.

The trial, which includes integrated process and economic evaluations, builds on development work which examined barriers to early uptake of antenatal care in Newham, London (REC ref. no. 10/H0701/88),see references [1], [2] and feasibility and pilot studies (see below).

Background

Antenatal care is an important public health priority as it has the potential to impact positively on women's health during pregnancy and upon the subsequent life-course of women and their children. Women from socially disadvantaged and ethnic minority groups often have

[1] **R**esearch for **E**quitable **A**ntenatal **C**are and **H**ealth in Pregnancy

difficulties with accessing antenatal care [3] and report more negative experiences with care, despite having potentially complex social and medical needs [4]. Lack of engagement with antenatal care has been associated with adverse pregnancy outcomes including low birth-weight, neonatal mortality and maternal mortality [5,6,7].

Models of group antenatal care such as 'Centering Pregnancy' combine conventional aspects of antenatal assessment with information sharing, including group discussion and learning, and the opportunity for social support for pregnant women. It is facilitated by health professionals (often midwives) for small groups of women with similar estimated due dates (and potentially their partners). To date, group-based models have been successfully implemented in a number of countries worldwide, including Australia [8], Sweden [9] and the U.S. [10]. Antenatal care configured in this way has been shown to increase women's satisfaction with care and has improved health and safety outcomes such as pre-term birth and low birth-weight [11,12,13].

Antenatal care for women in groups addresses multiple factors that have been found to be associated with women's negative experiences of antenatal care [14,15,16,17]. As each appointment lasts for approximately two hours (compared with approximately 15-30 minutes for a standard antenatal care appointment), and is facilitated by the same health professionals at each session, this model increases the amount of time that a pregnant woman spends with care givers, e.g. midwives [8,17], and enables continuity of carer [18]. It also provides for social support amongst group members, who, in our setting, may have become resident quite recently and/or may have migrated from abroad, where, for these and other reasons (e.g. financial constraints, limited English language ability) they may not have optimal existing support networks. Helping to address some of the main problems vulnerable and culturally and/or linguistically diverse women experience with standard, fragmented care, continuity of carer has been found to be beneficial, delivering enhanced communication and interpersonal rapport [19,20,21].

Furthermore, providing antenatal care within small groups promotes discussion and potentially more effective learning for and among women, rather than solely relying on a health professional as the source of "expert advice". It is also pertinent to note that many women living within the areas to be studied in this trial do not currently have access to traditional antenatal education classes for various reasons. It is expected that this new approach will promote women's empowerment, giving them more of 'a voice', enhancing informed decision making, and enabling them to tailor antenatal care more closely to their own needs. Significant benefits have been associated with such empowerment. If women feel that they have more autonomy and choice, this has been shown to increase their sense of control around birthing, and subsequently, this has the potential to increase their satisfaction with the birthing experience. How women experience birthing, whether as a positive and affirming life event or as a traumatic, negative experience, has the potential to affect their wellbeing and that of their children for the future life course [22, 23, 24, 25, 26]. The group approach also encourages women to engage in more self-monitoring, with the aim of increasing knowledge and confidence, again, these factors have been shown to be significant in increasing the likelihood of a positive birth experience [27, 28, 29, 30].

Although group antenatal care has been shown in other settings to be effective for improving women's experiences of care and for improving other maternal as well as newborn health outcomes, these outcomes have not been formally assessed in the UK. A recent systematic review of group antenatal care concluded that more high-quality studies of its effectiveness are needed to establish whether positive findings are widely applicable [31]. The expected health improvements from group antenatal care are in line with national and local aspirations for reducing inequalities and improving the health and wellbeing of women and children [25]. We are therefore proposing to evaluate robustly the effectiveness and cost-effectiveness of group-based antenatal care in enhancing women's experience of antenatal care, increasing its relevance and value to women, and improving outcomes for mother and baby, particularly

amongst women from ethnically, culturally and linguistically diverse and disadvantaged areas who are more likely to experience poor outcomes [32,7]. The trial will also deliver real-time evidence to shape the delivery of Better Births, the major new national policy agenda for maternity services [33]. The model of group antenatal care we have developed directly translates the recommendations of Better Births into practice (e.g. increasing continuity of carer, personalised care, and integrated multi-professional working).

In line with recent guidance [33,34], the feasibility work and pilot trial, that has preceded this protocol for a full trial has enabled the research team to understand and address the local and UK national challenges that any group-based model of antenatal care needs to be tailored to meet and to develop and test the methods for the full trial. This work is as follows:

- A feasibility study including extensive qualitative work and three 'test' pregnancy circles which developed and tested the bespoke model (REC Reference: 15/WA/0369). This showed that the model is both feasible to deliver and acceptable to service providers and local mothers from the diverse community in which it was tested. Various aspects of the intervention were refined as a result of this work.
- A pilot randomised controlled trial which aimed to determine the optimum methods for testing the effectiveness of Pregnancy Circles in an NHS-setting serving populations with high levels of social deprivation and cultural, linguistic and ethnic diversity (REC reference: 16/NS/0090). This demonstrated that: there were sufficient numbers of women eligible for participation; the required consent rate could be achieved; sufficient number of women took up and continued with Pregnancy Circles care; primary outcome data was available for the study via routine maternity data; response rates for questionnaires (secondary outcome measures) were acceptable.

As a consequence, the Pregnancy Circles model is now ready to be tested in the full trial.

5. TRIAL OBJECTIVES

This trial has the following aims:

a) To assess whether Pregnancy Circles (group-based antenatal care) improves the health of babies compared with the standard individual model of antenatal care.

b) To assess whether attending Pregnancy Circles improves maternal outcomes such as empowerment and post-natal depression, as well as increasing women's satisfaction with antenatal care.

c) To assess cost-effectiveness, intervention mechanisms, and acceptability of group-based antenatal care to women and staff and issues relevant to future sustainability and wider implementation in the NHS.

6. METHODOLOGY

Design

An individual randomised controlled trial, with integral process and economic evaluations.

Setting

The trial will be carried out within the maternity services of around 12 NHS Trusts within London and the surrounding areas including Barts Health NHS Trust, Whittington Hospital NHS Trust, Lewisham & Greenwich NHS Trust, West Hertfordshire NHS Trust, East Suffolk and North Essex NHS Foundation Trust, Princess Alexandra Hospital NHS Trust, Worcestershire Acute Hospitals NHS Trust, Basildon and Thurrock University Hospitals NHS Foundation Trust, Ashford and St Peter's Hospitals NHS Foundation, Royal Free London NHS Foundation, East Sussex Healthcare NHS Trust. A number of 'Pregnancy Circles' (i.e. one group of women who have their antenatal appointments together) will be run within the catchment areas of each of these Trusts by midwives from the local service[2]. The exact number and specific area within the catchment area of each service in which the 'Pregnancy Circles' will be run will largely be determined by practical issues, with decisions being made in consultation with service managers. We anticipate that around 7 – 14 Pregnancy Circles will be run by each service. The Circles will run in the usual working area of the midwives who facilitate the groups.

Population

a) Inclusion criteria

- Women who are currently pregnant and registering for antenatal care with one of the included maternity services. Included women will need to live within, or near to, the working areas of the local midwife group facilitators and have an estimated delivery date that fits with those of a proposed group. They do not have to be able to speak English to participate. The following categories of women can be included:
    - primiparous and multiparous
    - "low" and "high" obstetric risk including requiring specialist services (HIV +, diabetics)
    - with additional needs e.g. physical disabilities
    - with additional social needs e.g. have a current/past 'Child in Need' plan
    - with obstetric complications e.g. those with multiple pregnancies (twins)
    - teenagers (16-19)

  Where specialist pathways are in place (e.g. diabetes, twins, teenagers etc.), referral to these should be made. It may be appropriate to offer these women both Pregnancy Circles and the specialist pathway (not all will want the additional Pregnancy Circles appointments, but some will).

- Midwife facilitators who are employed by the maternity services involved in the trial, and who have attended study specific training provided by the research team or through a specialist MSc module at City, University of London ('Advancing Midwifery Practice: Facilitating group antenatal care). This module was developed in response to the training needs of midwives within the REACH Pregnancy Programme.

[2] We are currently discussing with individual sites how many Pregnancy Circles they will be able to run

b) Exclusion criteria

- Non-pregnant women.
- Women registered for antenatal care at other NHS services outside of the NHS Trust maternity services taking part in the trial.
- Pregnant women who live a considerable distance from the working area of the facilitating midwives.
- Pregnant women whose estimated delivery dates, at the time of recruitment do not fit with those of a proposed group.
- Pregnant women who decline to take part
- Pregnant women who are under 16 years of age at the time of recruitment.
- Pregnant women with a documented learning disability.
- Pregnant women who from booking are identified as being
- particularly vulnerable. Services are configured differently in each Trust so a decision about who is considered 'vulnerable' will be made locally. Women considered to be particularly vulnerable may include those with: current severe mental health concerns requiring specialist input/services/admission; substance misuse problems requiring specialist input/services; child protection concerns (including previous removal of children).

Local clinicians should make decisions about offering vulnerable women trial participation on a case by case basis. It should not be automatically assumed that women with complex needs cannot be offered participation in the study. As general rule, women should be offered participation so that they can make their own decision about taking part or not.

An additional site/circle specific exclusion criterion also applies. Before recruitment to each Pregnancy Circle starts, facilitating midwives at each site will 'put a cap on' the number of different languages spoken where interpreter support is required, in a Circle. Once recruiters have reached this 'cap' for each Circle any subsequent pregnant women who meets the inclusion criteria but requires interpreter support for a language different from that/those already included in a Circle, will be deemed ineligible and not offered trial participation. See p 16 more information on this issue.

Outcome measures

a) Primary outcome

A 'healthy baby' composite consisting of the following 4 components:

1. Live baby (i.e. no stillbirth after 24 completed weeks of pregnancy and no neonatal death within 28 days of the birth)
2. Born at term (37 weeks and above)
3. Appropriate weight for gestational age (GROW centile >9.99 & < 90.01)
4. Not admitted to a Neonatal Intensive Care Unit (NICU)

A baby is considered a 'healthy baby' only if the answer to all above 'questions' 1) – 4) is 'yes'

b) Secondary outcomes

1. Women's empowerment (includes involvement in decisions about care)

2. Spontaneous vaginal delivery (SVD) defined as a woman who delivers vaginally without forceps or ventouse
3. Women's satisfaction with maternity care
4. Continuity of antenatal care
5. Attendance at antenatal care
6. Health service usage
7. Social support
8. Self-efficacy
9. Prenatal stress
10. Caesarean delivery (planned, emergency, none)
11. Infant birth weight, defined as low if less than 2500g
12. Place of birth
13. Breast feeding initiation
14. Breast feeding continuation and exclusivity
15. Postnatal depression
16. Health Literacy
17. Postnatal symptoms
18. Mental wellbeing
19. Live baby (i.e. no stillbirth after 24 completed weeks of pregnancy and no neonatal death within 28 days of the birth)
20. Born at term (37 weeks and above)
21. Appropriate weight for gestational age (GROW centile >9.99 & < 90.01)
22. Not admitted to a Neonatal Intensive Care Unit (NICU)

Intervention

Pregnancy Circles are being implemented by the participating trusts as part of their service development. Each 'Pregnancy Circle' will consist of around 8 - 12 pregnant women who have estimated delivery dates within the same approximate one month period. The women who consent to participation in the study and are randomised to the 'Pregnancy Circles' trial arm will receive all of their usual midwife-led antenatal care within this group. Any necessary appointments for consultant or specialist care will be carried out as per the usual care pathways outside of (and in addition to) the group. Where possible, depending on the venues available locally, a free creche will be run for Pregnancy Circles participants to use for their pre-school aged children.

Those women randomised to the 'Pregnancy Circle' trial arm will start attending at the first routine midwife appointment that follows their antenatal booking appointment (the 'booking appointment' which usually takes place between 8-12 weeks of pregnancy). This first routine appointment is on average at 16 weeks of pregnancy (14-18 weeks). The pilot trial demonstrated the importance of making contact, via a range of routes, with the women prior to the first Pregnancy Circles to ensure understanding of what women are required to do. Thus, in the trial facilitating midwives will use a combination of letter, text and/or phone calls to participants to confirm arrangements for the first Circle. Trust records will be checked by the facilitating midwives prior to making contact about the groups to make sure pregnancy loss has not been recorded for any of the women. Subsequently the women will continue to attend the Circle according to the normal antenatal care schedule. Any woman who chooses to discontinue the group care during pregnancy will transfer to the conventional care pathway and will remain in the trial, unless she requests withdrawal. Any woman who must discontinue with the group care due to pregnancy loss, will be able to contact their named midwife and be referred to medical services and sources of support, as appropriate. Any woman who does not attend a group session will be contacted by the facilitating midwives to ascertain the reasons for this. If appropriate, the woman will be invited to attend the next

group session, and the Trust's usual 'did not attend' (DNA) protocol will be followed, in the meantime, i.e. being offered an alternative one-to-one appointment to make up for the missed appointment. This same process will be followed for non-attendance at subsequent Circles.

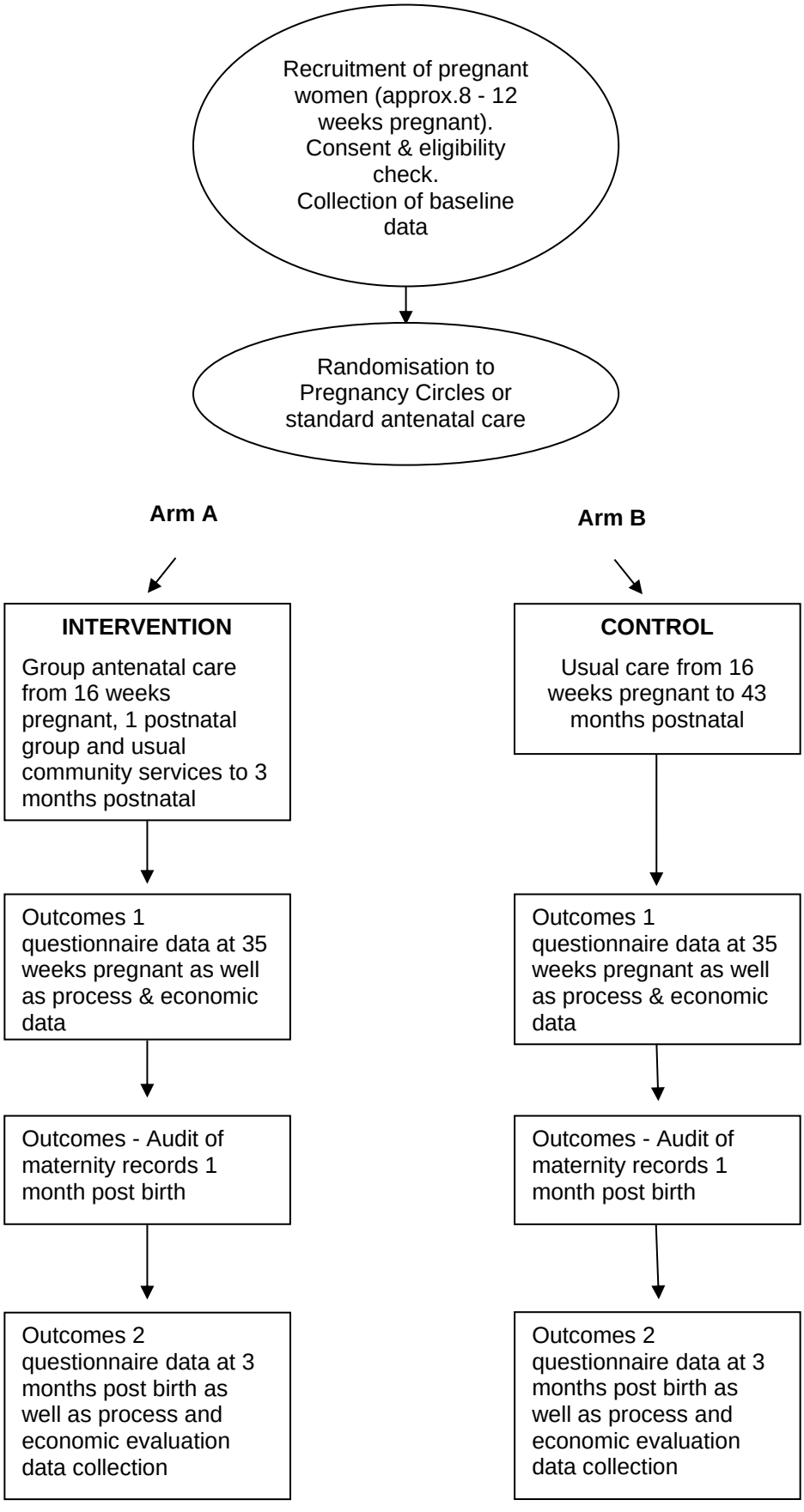
Each Pregnancy Circle group session will be facilitated by two midwives supplemented with interpreters and/or other support staff as appropriate. Midwives receive training and ongoing support to facilitate the Pregnancy Circles and are provided with a manual for running the Circles. The same two midwives aim to facilitate all the sessions for a Pregnancy Circle and each woman will have one of these midwives as their Named Midwife. A third midwife will be identified to provide support as required such as covering sickness or annual leave. These midwives will have all undergone bespoke training in delivering Pregnancy Circles group antenatal care and will have their Pregnancy Circles time included on the service roster. They will also have been trained in the requirements of the trial, for example documentation of attendance.

Women participating in the 'Pregnancy Circle' will receive the same number of antenatal appointments as women receiving standard care, according to the primipara schedule outlined by [24] (this means that multiparas will receive two additional appointments, compared to conventional care). Women who participate in the 'Pregnancy Circle' will receive standard intrapartum, postnatal and health visitor care, but they will also be invited to a postnatal reunion group held approximately one month after the last estimated due date of the women in the group. Where possible a local health visitor (HV) will co-facilitate this reunion postnatal group with the midwives and will also meet the women during one of the antenatal Circles. Women in the control group will continue to have standard antenatal, intrapartum and postnatal care and then standard health visitor care.

There will be a total of eight antenatal group sessions each of which will last for approximately two hours. The first part of each session will involve 'self-care activities' (e.g. women will be encouraged to take an active part in their antenatal care by testing their own urine, taking their own/each other's blood pressure and writing the results in their notes). Following these checks, the sessions will involve short one-to-one sessions with one of the midwife facilitators for individual health checks (e.g. abdominal palpation) which will take place on a mat in the corner of the room ('one-to-one time') while the rest of the group has a group discussion facilitated by the second midwife. Women will be allowed to request more privacy for one-to-one time. Any concerns regarding a group member's blood pressure or scan or test results, or any individual psychological or social issues, can be addressed during 'one-to-one time' or at the end of a session by a woman's lead midwife, as appropriate, whilst the other midwife continues facilitating the group. As with usual care, women will be referred to other specialist services for routine and additional appointments, blood tests and scans as appropriate. The postnatal session will use a similar approach but without one-to-one time. The focus of this session will be maternal postnatal wellbeing, wellbeing of the baby and infant feeding support.

Midwife/HV facilitators will document the appointment in the same way and have exactly the same responsibilities towards the women as they would during conventional care. During the first group session, the facilitating midwives will develop ground rules of confidentiality in partnership with the women, asking the participants to respect each other's privacy and confidentiality regarding what is shared within the group. The views of the group will be ascertained regarding how and when partners are involved in the sessions.

Scheme Diagram



7. STUDY PROCEDURES

Trial procedures

The trial will use PCTU standard operating procedures (SOPs) where these are available. Other SOPs will be written by the research team as necessary.

Language support

The study population in most of the trial sites is extremely diverse in terms of languages spoken. Interpreter support for women is therefore required for the following: recruitment, data collection, participating in the Pregnancy Circles. Based on our findings from the pilot trial we will use a combination of some or all of the following forms of language support, in consultation with each participating Trust:

1. Interpreters employed by participating NHS Trusts.
2. Interpreters from an external agency
3. Researchers who speak languages required other than English
4. The Language Shop phone interpreting
5. Informal support from family/other pregnant women.

The Language Shop will only be used for recruitment and follow-up data collection when other forms of language support are not available. A contract for this service will be put in place so that it is available for ad hoc use. Support from a family member may be appropriate at recruitment/consent and some data collection if the woman prefers this; where this is a possibility a woman will be given a choice of different types of support available. The Language Shop will not be used for Pregnancy Circles, as face to face language support is more appropriate in this instance. Additionally, family and friends will not be appropriate to provide language support in the groups. However, from the pilot, we have learnt that some women prefer, in the Pregnancy Circle, the support of others in the Circle who speak their language rather than an official interpreter. This preference will be supported, where other language speakers are participants and are willing to take on the role, with the option to engage an interpreter if a woman changes her mind.

The pilot trial demonstrated the complexity of arranging language support that was acceptable to all involved parties. Issues included: minimising the burden on, and inconvenience, to booking clinic staff when an interpreter was required for study purposes; ensuring that there was minimal turnover of interpreter for a woman attending a Pregnancy Circle; ensuring that interpreters fully understood their support role in the Pregnancy Circle.

If needed, we will carry out the following, in each site, for services involved with language support:

- Training sessions about the trial for interpreters
- Liaison with the staff who book interpreters for routine maternity care services to support them in doing this for trial purposes – including providing continuity of interpreter for a woman in the Pregnancy Circles (covered in facilitating midwives' training)
- Attendance at meetings as appropriate to facilitate joint working.
- Extending the recruitment period to include late bookers who are more likely to be from migrant and other vulnerable groups.

We also learnt from the pilot trial that having more than one additional language to English, requiring interpreter support, spoken by women in a Circle presents a potentially unacceptable burden to the facilitating midwives, particularly when a midwife is new to delivering the intervention. As such, facilitating midwives in each site will 'put a cap on' how many different languages requiring interpreting support can be spoken in a Pregnancy Circle at their site. Recruiters at the site will recruit accordingly. For example, if the midwives

decide that they want to run their first Pregnancy Circle with only one additional language spoken, then once the first non-English speaker who requires an interpreter has been randomised, only non-English speakers who speak this same language and require an interpreter will be offered trial participation during the recruitment for this particular Circle. Non-English speakers who speak a different language, but don't require an interpreter, can be recruited. As facilitating midwives become more experienced at running the intervention, they may increase the numbers of different languages, where interpreter support is required, in a Circle. If this is the case, they will communicate this to the recruiting staff. Thus, specific criteria for recruitment of women requiring interpreter support can differ between different Circles during the total recruitment period at a site.

As not speaking English and low literacy levels often co-exist in an individual, we did not initially produce translated versions of trial documents aimed at participants/potential participants, other than a translation of the phrase "*We can provide help from an interpreter if you would like this' in 5* relatively common languages on the front of the PIL. Instead we focussed on provision of good verbal interpreting support. Subsequently, at the suggestion of site recruiters, we produced the PIL and consent form translated into Romanian. This is one of the most common languages, other than English, spoken in our trial sites and one where speakers appear relatively unlikely to have a acquired a good command of English. If these translated documents prove useful, we will consider doing the same with some other languages.

Recruitment of Participants

Sample size

The study will aim to recruit 1732 women. Half of the recruited women in each area will be randomised to take part in the 'Pregnancy Circles'; and half to receive standard antenatal care.

Screening, recruitment and consent

Potential participants will be recruited from women attending their first midwife appointment to register with the included maternity services (the 'booking appointment', which takes place when the majority of women are between eight and 12 weeks pregnant) and/or at the dating scan appointment (which takes place when women are around 12-13 weeks pregnant). All women who fit the inclusion criteria, and are attending a clinic where a recruiter is present, will be approached.

Personnel carrying out recruitment and consent will be REACH team researchers, and research midwives or other research staff employed by the study's NHS Trusts and/or funded by the clinical research network.

The booking appointments are mostly held in centralised 'antenatal booking clinics' within the maternity services. In any site where this is not the case (for example they are held in community settings), specific arrangements will be made based on discussions with local staff. For some sites, they may deem it more appropriate and feasible to recruit women at their scan appointment which are held within the hospital sites. Both options are acceptable and at the discretion of each local site. The process of screening, recruitment, and consent is the same if at the booking or scan appointment. In the pilot trial a local research midwife (with authorisation to access patient data) worked with the antenatal booking clerk in each area to identify women who fitted the inclusion criteria, prior to the booking appointment. REACH researchers provided support where possible, but were limited in what they could offer as they were not able to access patient data. We learnt from the pilot that administrative staff were often over-burdened and the demands of the study presented a barrier to their own work. Therefore, in the trial we will identify service side or locally employed research personnel to screen for eligible women (as per the pilot). In addition, we

have applied to, and received, Confidentiality Advisory Group (CAG) permission to access the required patient data without consent (Section 251) (Approval received 18 May 2018; reference, 17/CAG/0186**)**. This means that a member of the research team can, if required, provide support in carrying out this task. If this additional support is required the patient data that the research team member will require is: name, address, date of birth, expected date of delivery, presence of a documented learning disability or other vulnerability (which may require a referral based on a service's local provision regarding vulnerability). An introductory letter and participant information leaflet (PIL), about the research, will then be provided to the women who fit the inclusion criteria. This will allow potential participants time to consider participation, and seek more information if desired, before they are approached about the research at their booking appointment (see below). The letter will be posted from the hospital site which means that the patient data will not be removed by researchers from the site. Any notes made by the research team, containing patient data, will remain on the hospital site and will be destroyed as soon as the letters have been despatched. Our two lay co-investigators, a group of 8 pregnant women who were participants in the pilot trial, and a local Maternity Services Liaison Committee have all been consulted on this issue and have found it acceptable From the pilot we learned that many women did not appear to have read (or did not remember receiving) the PIL, so another copy will be provided prior to recruitment and women given time to read it. If women are recruited at the scan appointment, the PIL can either be posted out to participants or provided to them in person by their booking midwife (with brief information detailing that the women may want to consider participating but may be approached to discuss further at their scan appointment).

Immediately prior to the booking clinic or scan appointment (either the day before or first thing on the day) the notes of the women due to attend who fit the inclusion criteria will be 'flagged' by those carrying out recruitment. Once attending their booking appointment or scan appointment, clinic staff (reception and midwives) will be asked where possible to: mention the study to the women with flagged notes, offer another copy of the PIL, explain that a researcher will approach them to invite them to discuss participation. The researcher will approach the woman and offer a verbal explanation of the Pregnancy Circles, the study and the concept of randomisation will also be given by the recruiter and women will have the opportunity to ask questions. At recruitment, any language requirements will be noted and women will be asked if they would like language support for recruitment (and other aspects of the study).

It will be explained, to all women approached, in writing and verbally that they can withdraw at any time if they so wish. If a woman is unsure about whether she wishes to participate in the trial she will be able to consider this for up to a week after the booking visit (see below for detail). Data handling and security is explained as follows in the PIL.

The study will follow the Data Protection Act 2018. All information you give us will be stored securely and treated as confidential. We will not use your name, or any other information that could identify you in questionnaires or any reports on the research. The anonymous data from the study may be kept in a data archive for other researchers to use in the future. Any data not suitable for other researchers to use will be kept in a secure data archive. Data will be reviewed every 5 years and any information not needed will be destroyed.

Women who choose to participate in the trial will be asked to sign a paper copy of the consent form and to fill in a self-completed baseline questionnaire. Another time will be arranged for those who require language support for consent and baseline completion, if appropriate.

The baseline questionnaire will be completed on paper. The intention was to also provide this electronically on a computer tablet. The electronic version of the baseline questionnaire was developed and tested in the pilot trial using the electronic patient recorded outcome tool (REDCap). The PCTU provide and manage REDCap. Despite attempts to introduce use of

an online version of REDCap for baseline completion at recruitment this has not proved possible primarily due to inadequate WiFi in many of the participating sites. Thus, to date the baseline questionnaire has been completed on paper only. This paper-based only system, for baseline questionnaires, will now continue in all trial sites to the end of recruitment. REDCap will continue to be used for online questionnaire completion, via a survey link emailed to participants, for both follow up questionnaires. Baseline questionnaire data is entered onto REDCap by the central research team once the paper baseline questionnaires are sent securely from the sites, and in advance of the required first follow up questionnaire completion date.

Our pilot demonstrated that it is feasible to recruit the required number of women within appropriate timescales (i.e. 3-4 weeks for each Pregnancy Circle). If this does not prove to be the case in any site, or a number of participants miscarry following consent, there will still be time to 'top up' the recruitment before the Pregnancy Circle starts. Where a recruit does miscarry we will not contact them to avoid compounding their distress. Recruits are informed in the PIL that their data will not be used in the study if they miscarry.

A number of meetings and events about the study will be run by the research team for service side staff to provide information and discuss staff support needed, in advance of the study starting.

Baseline questionnaire completion

Completion of the baseline questionnaire is required prior to trial arm allocation being revealed to the women in order that knowledge of the type of care they will receive does not influence their responses. The baseline questionnaire includes demographic questions, a limited number of outcome measures, and some questions relating to service preferences (see Table 1 for detail). PPI feedback on the draft baseline questionnaire, prior to the pilot trial, showed that for this to be acceptable to the diverse community in the study population it is imperative that it is as short and simple as possible.

Some women who decide to participate may not have time to complete the questionnaire in the clinic. These women will be given a hard copy of the questionnaire and a pre-paid addressed envelope. They will be asked to submit their completed questionnaire within a week of their booking appointment. If the questionnaire is not received by the research team, after a week has passed, a phone call will be made or email sent (depending on a woman's preferred route of communication). A second contact will be made after another 2-5 days, if the questionnaire has still not been received.

If a woman is unsure about whether she wishes to participate in the trial she will be able to consider this for up to a week after the booking/scan visit. She will be given a hard copy of the consent form and baseline questionnaire to take away, to be completed at home if she decides to participate. Stamped addressed envelopes will also be provided. She will be asked if she is happy to give her telephone number/email address to the researcher so that reminder contact/s can be made to clarify whether she is interested in participating. A first follow up contact will be made, by the research team, after about 2 days of the booking appointment visit (to offer support in reaching her decision) and again around 5 days later, if she has not responded in the meantime. The pilot trial demonstrated that if too much time is allowed to pass before contact is made it is more difficult to re-engage a woman. If a woman does not wish to give this contact information, she will have the option to call the research team using the number given on the PIL. If a woman decides to participate, she can return the completed consent form and questionnaire in the post. Alternatively, she can just post the consent form and complete the questionnaire over the phone with a researcher (and an interpreter if required). For those women who do not speak English or who have limited literacy the researchers will offer to make home/community visits to administer the questionnaires accompanied by a bilingual health advocate where required.

Women will receive a £10 voucher on receipt of the completed baseline questionnaire. This

will be handed to the woman or sent in the post according to how the questionnaire is returned to the research team.

Site staff are responsible for safe delivery of the recruitment paperwork to the central research team. They will send this, by tracked postal services, on a fortnightly basis. This regularity is required to allow time for data entry onto REDCap (of email address and baseline data), by the central research team, before automatic dispatch of an email with a link to the first follow up questionnaire is due, at 35 weeks of pregnancy. Guidance for safe and timely dispatch of this paperwork is provided for site staff.

A comprehensive patient identifiable database will be kept by the research team in order that all contacts and actions, related to recruitment, are recorded. This will be built and managed, to ensure data security, by the PCTU data management team as per standard procedures.

Local researchers carrying out recruitment will regularly email a version of the screening log that has been de-identified, to the trial manager. This will be requested on a weekly basis, in the early stages of recruitment at a site, with the frequency reduced once recruitment is successfully established.

During the recruitment phase the research midwife, and where possible another member of the research team, will attend a regular antenatal clinic team meeting to discuss and problem-solve any issues around recruitment/consent. The research midwives will be well supported by the research team, as well as by other research midwives and other types of research staff within the Trusts.

Randomisation procedures

Randomisation will be carried out in the clinic, immediately following consent and baseline questionnaire completion, using a PCTU dedicated online randomisation system. Randomisation will be stratified by the location (site) of the Pregnancy Circle and how well a woman speaks English. The researcher recruiting the participants will input into the system, the women's study ID number (as assigned by the researcher), the centre code and women's initials. English speaking ability is assessed using question 5 in the baseline questionnaire and for the purpose of randomisation dichotomised into a) well/very well or b) not well/not at all. The randomisation service will allocate the women to either Pregnancy Circles or usual care in a 1:1 ratio and, if recruited in person, she will be told her allocation status face to face straight away. She will also be given information about the type of care she will have. For women in the control arm this will be as per local procedures. For example, she may be given her next appointment details there and then or she may be told this will be sent to her in the post. For women in the intervention group this will include a Welcome Pack detailing information on the venue and dates/times of all the Pregnancy Circle sessions as well as contact details for the facilitating midwives.

For women who want additional time to think about participation, if they decide that they do want to take part, randomisation will be arranged as soon as the completed baseline questionnaire has been received by the research team (in the post or over the phone) as well as the signed consent form. The participant will be informed of their trial arm status over the phone or by email. If by email a reply email confirming receipt and understanding will be requested. After 2 days if a reply has not been received by the research team follow up will be made, as appropriate, until a woman confirms that she understands her trial arm allocation status.

All women in the intervention arm will be given, or sent in the post, a copy of their completed consent form and an 'Information for Health Care Professionals' sheet to be inserted into their handheld notes. This information sheet will explain that a woman can either have all her routine care in her Pregnancy Circle (including any care that she would otherwise have had from her GP) or she can if she wishes, continue to have any routine antenatal appointments with her GP, in addition to Pregnancy Circles care. It will be noted in the site file that the

'Information for Health Care Professionals' sheet has been added to the handheld notes. Women in the control arm will be given or sent a copy of their consent form for inclusion in their hand-held record.

A sticker will be placed on patient hand held records that specifies trial participation and allocation.

Participant outcomes data collection

Participant outcomes data will be collected in the trial via two routes: questionnaires completed by the participants and routine maternity service data collected from the Trust.

Outcomes questionnaires

The two outcomes questionnaires will be sent out to intervention and control group participants as online and/or hard copies. Using the electronic patient recorded outcome tool (REDCap) a survey link will be emailed out to participants who indicated at recruitment that this was their preferred route; paper versions with reply envelopes and a link to the online version will be sent to all other participants. All women will be offered a £10 voucher for each of the two outcomes questionnaires they complete. These will be posted to women on receipt of their completed questionnaire.

The outcomes questionnaires will include outcome measures and some process questions relating to attendance at antenatal care. Table 1 (see below) provides detail about the content of each questionnaire.

In advance of contacting women about these questionnaires, the research team will check with site staff e.g. site PI, facilitating midwives (intervention group) and/or antenatal clinic staff (control group) that there are no reasons (for example the loss of a pregnancy) why a woman should not be approached. Where a woman requires language support, a researcher will work with an interpreter to arrange completion over the phone or face to face in a setting of her choice. Any woman who has not returned a completed questionnaire 1 week after sending out will be sent a reminder email (or phone call if no email address) and then a phone call after a second week to encourage completion.

Content of outcomes questionnaires/routine maternity data proforma

Table 1. Data measures for Pregnancy Circles Trial

Baseline measures: (c 8 -12 weeks pregnant)	**Outcomes questionnaire 1** **(35 weeks pregnant)**	**Post partum maternity records audit – data items collected for outcome assessment**	**Outcomes questionnaire 2** **(3 months postpartum)**
Social support (Duke Social Support Scale) **Self-efficacy** (*Pearlin Mastery Scale)* **Prenatal stress** (*Revised Prenatal Distress Questionnaire)* **Health-related quality of life** (*EQ-5D)* **Emotional well-being** *(Short Warwick-Edinburgh Mental*	**Empowerment/involvement in decisions about care** (Pregnancy-related empowerment scale PRES) **Self-efficacy** *(Pearlin Mastery Scale)* **Prenatal stress** (Revised Prenatal Distress Questionnaire) **Health service usage** Maternal self-report of their use over the previous 3 months of a variety of primary health services (GP, health visitor, social work and hospital doctor), A&E services, antenatal admissions.	***Data items for Primary outcome*** **Healthy birth composite.** 1) live birth (from 24 completed weeks of pregnancy and no neonatal death within 28 days of delivery) 2. gestation at delivery 3. birth weight (plus gender for GROW) 4. admitted to NICU ***Data items for secondary outcomes***	**Social support** (Duke Social Support Scale) **Self-efficacy** (Pearlin Mastery Scale) **Involvement in decisions about care/satisfaction with care** *(Questions from the Care Quality Commission's Maternity Survey)* **Breast feeding continuation and exclusivity** **Health service usage** maternal self-report of their use over the since the birth for themselves

Wellbeing Scale (SWEMWBS) **Demographic questions** Age Ethnicity Language Parity Education Tenancy	• Attendance at antenatal care • Reasons for non-attendance **Health-related quality of life** (*EQ-5D)* **Continuity of care** **Satisfaction with care** **NHS** **Emotional well-being** (*Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS)*	**Spontaneous vaginal birth** (without instruments) **Caesarean delivery** (planned, emergency, none) **Epidural/Spinal/General analgesia use in labour** **Induction** **Breast feeding** **Actual Place of birth** **Number of nights in hospital (mother/baby)** **Attendance at antenatal care**	and their baby of a variety of primary health services (GP, health visitor, social work and hospital doctor), A&E services, late antenatal admissions, and uptake of infant immunisations at 2 and 3 months). **Postnatal Depression** (*Edinburgh Post Natal Depression Scale, physical screening*) **Postnatal Symptoms** **(***NPEU checklist***)** **Health-related quality of life** (*EQ-5D)*

Routine Maternity Services Data

As table 1 indicates, some participant outcomes data (including the primary outcome data) will be assessed through patient records, rather than from self-completed questionnaires. We will use two routes to access these data: 1) through electronic patient records and 2) through an audit of paper maternity notes.

The research team has developed SOPs and proformas for the data transfer processes. These have been tested, in the pilot, and amended as appropriate.

We will supply the informatics team, who will carry out the transfer of electronic data, with a list of participants' hospital numbers and study IDs, so no names will be required. An SOP has been generated for the secure transfer of data from the trust informatics departments to the PCTU. The data management team at the PCTU have supported the writing of a data management plan that includes detail on these processes, in line with PCTU SOPs on data formats and transfer procedures to ensure data security.

For the paper maternity notes, local CRN research staff who are blinded to the allocation to study group will conduct an audit by extracting data manually from the participants' hospital paper records within the hospital setting. The proforma used will anonymise the information collected, using study ID numbers. The data will be entered onto an electronic database and securely transferred to the PCTU using the SOP developed by the data management team at the PCTU.

We will use either, or if necessary, both of the two routes according to what is appropriate in the various sites. Factors affecting this decision will include relative completeness of data and capacity to support the trial in local Informatics teams. We will collaborate with local staff to reach this decision.

During the final phase of the pilot trial (WP2) an algorithm will be developed to determine the binary primary outcome status – healthy or not healthy. The primary outcome value is coded as healthy only if all four components are 'yes'. If at least one component is 'no' then the baby is considered not healthy. We will provide instruction to the local informatics team asking them to code components 'admitted to NICU' and 'neonatal death' as yes/no and components 'gestational age at birth' and 'birth weight' as integers.

An Endpoint Committee will be set up for the main trial to assess any cases where there are uncertainties around primary outcome status. Members of the research team and a minimum of 2 clinicians will be on this committee.

Co-ordination of the data management process

The PCTU data managers will co-ordinate the data management process. Electronic systems will be put in place that automatically manage the process of sending out electronic questionnaires, vouchers and reminders for questionnaires. It will also involve supporting the integration of the outcomes data from participant questionnaires, electronic maternity records and maternity audit data. A statistical analysis plan will document the processes required to enable integration of the datasets in a manner that maintains standardisation of data and blinding of those involved in developing the analysis plan. All databases and analysis files will be stored on a secure server and accessed via a secure network. Access is restricted to authorised personnel only and via secure, password-controlled, role-based access.

Questionnaires will be identified only with study ID number, not with the woman's direct identifiers. Paper questionnaires will be stored in a locked filing cabinet in a pin code accessible office for the duration of the study. This data will be entered, by the research team, onto the REDCap database developed and maintained by the PCTU.

Blinding/ Unblinding

The participants and maternity staff will be unblinded to allocation, as will researchers conducting process evaluation observations and interviews.

Data informatics staff supplying outcomes information from electronic records and researchers accessing paper records for outcomes information will be blinded to intervention allocation. Those contributing to the analysis plan and conducting the analysis at the PCTU will be blinded to intervention allocation until the formal statistical analysis plan has been signed off and the database frozen for analysis.

Internal pilot

Within the recruitment period, there will be an initial internal pilot phase in which we will assess recruitment progress. We will use traffic light progression criteria to assess recruitment progress relating to the number of participants recruited, the total number of intervention Pregnancy Circles recruited to, and the number of Trusts/sites recruited. Data from the internal pilot will be presented to the Trial Steering Committee to support decisions on trial processes and continuation.

Process data

The aim of the integral process evaluation is to help understand the presence or absence of treatment effects, to identify any unanticipated or unintended effects, whether positive or negative, including adaptive systems effects (i.e. unintended adaptations in the maternity services); it will also measure potential contamination of the control group. We will explore the experiences particularly of women from clinically and socially high-risk and disadvantaged groups (including those a BMI ≥30 at booking). We will use the Consolidated Framework for Implementation Research (CFIR) to inform the evaluation in relation to the implementation of this model of care considering both the intervention and the context into which it is implemented in order to work out why certain outcomes are generated [36, 37]. In addition, Normalisation Process Theory will inform our analysis of the potential for future integration ('normalisation') of this model of care into routine maternity practice within the NHS. [38] Fidelity and acceptability will be measured and issues relevant for future sustainability and wider implementation will be highlighted. In addition, this approach will enable us to test and further develop the theory underpinning the intervention, enabling us to obtain a richer understanding of the outcomes. Three trial sites will also form case studies for more in-depth data collection. These will be purposively selected with the aim of achieving variation of cases. A combination of data collection approaches will be used in

order to come to a more complete understanding of the mechanisms triggered when the intervention is introduced. Observations, questionnaires, semi-structured interviews and focus groups will be used to gather data from women and care providers, in both the intervention and control arms in the case study sites.

a) Observations of Pregnancy Circles and standard care

Non-participant researcher observation will be conducted in the case study sites. A semi-structured observation proforma will be used to record the observations. Approximately 3 group sessions (across different 3 different Pregnancy Circles) and 3 standard care consultations will be observed in each of the 3 sites. Pregnancy Circles to be observed will be purposively selected for diversity of issues including: different languages spoken in the group, partner presence, mix of prima and multi-gravida, stage of pregnancy of the participants, and experience of the facilitators in delivering the intervention. In addition, some sites which are not part of the case studies but which warrant specific interest (i.e. are outliers, practising in an interesting way and/or consist of particular target women such as those with a high BMI) may also be invited to participate in observations and potentially more intensive observations (up to 8).

The potential that a participant's antenatal care sessions may be observed is briefly introduced in the PIL before written consent is gained to take part in the study. Additional verbal consent will be sought from the women and any partners before the group or individual consultation starts and they will be given an opportunity to ask questions. If anyone in the group wishes to withdraw consent this will be documented and their data will be excluded and they will be reassured that this will not affect their care. It is not practicable to only observe traditional care being delivered to women in the control arm of the trial, so all women attending identified clinics will have the study explained to them verbally and asked to give verbal consent to the observation. No identifying data will be collected during the observation and the focus of the observation will be on the midwife rather than the woman/partner. For women who do not speak English, where interpreting support is available, this will be used to provide information on the observation. If there is no interpreting support available, observation involving these women in standard care settings will not take place. If a woman in the control group having an individual consultation wishes to withdraw consent the observation will not be carried out. A researcher will contact the midwives providing care (whether intervention or control) in advance and ask for their consent to attend a Pregnancy Circle or standard care appointment. On the day midwives will be given a chance to ask questions and will be asked to sign a consent form before the observation begins. The aim of observations of individual consultations is to facilitate the reporting of a description of standard care; for observations of the Pregnancy Circles the topic guide will be used to capture data to support the measurement of fidelity.

b) One to one interviews/focus groups with key stakeholders

Selected participants in the 'Pregnancy Circles', in the case study sites, will be offered the opportunity to have a one to one semi-structured interview after their baby has been born. A purposeful sample of approximately 7 participants (in each case study site) will be interviewed at a time and location of their choice, either over the phone, at home or in a community venue with an appropriate level of privacy according to participant preference. Women may choose to have their partners and/or children with them during the interview. Interviews will be between about 30 - 60 minutes in length. Women who have suffered an adverse neonatal outcome (stillbirth, neonatal death, admission to the neonatal unit) will not be interviewed unless they specifically request it. The PI at each site will confirm whether women can be contacted postnatally. In order to provide an understanding of the typical experience of maternity care in these sites, a comparable sample of women in the control group, who received standard antenatal care, will also be invited for interview.

The purpose of the interviews will be to explore participant's experiences and satisfaction with their antenatal care and their perceptions of its effects. Sampling will be purposive, to

focus on understanding the experiences of clinically and socially high risk and disadvantaged groups in both intervention and control arms of the study. The views and experiences of women who received language support as well as those who have chosen to leave Pregnancy Circles to return to standard care will also be sought. Women participating in these interviews will be given a £10 voucher as a 'thank you' for their time and effort.

In order to provide context to data collected from women, a purposeful sample of midwives and other relevant staff and key stakeholders (recruiters, clinical commissioners and patient group representatives) in the case study sites (including managers at different levels) will be offered the opportunity to take part in a brief (up to 30 minutes) interview about their perceptions of the issues relating to delivery of and retention in the Pregnancy Circles, sustainability of this model of care, potential contamination. In addition, some midwives or other relevant staff and key stakeholders who are not part of the case studies but who are outliers or practising in a unique way may also be invited to interview.

In addition, as part of the nested PhD study, a group of up to 20 women with a BMI ≥30 (both in the intervention and control arm) will be invited to take part in two interviews (antenatal and postnatal) to explore their experiences of antenatal care. Midwives facilitating Pregnancy Circles where participants had a BMI ≥30 will also be invited to an interview to explore their experiences of delivering care to these women. The procedure for approaching these women and midwives will follow the same produces outlined above.

Other sources of data

The process evaluation will also draw on the following documents when analysing the data for the process evaluation, to provide context and background:

- Closing interviews with link researcher for each study site
- Field notes from researchers on training sessions run for facilitating midwives
- Facilitating midwives' reflective forms (with their permission)
- Research team processes and implementation records (eg meeting minutes, working documents)

Process evaluation data analysis

All qualitative observational and interview data will be entered into data analysis package NVivo 12, and analysed thematically, with reference to the Context-Mechanism-Intervention framework developed at the start of the study and subsequently refined throughout its different stages (literature review, feasibility and pilot testing). Triangulation across data sources will be carried out. We propose to use the Consolidated Framework for Implementation Research (CFIR) to inform the evaluation in relation to implementation of this model of care (Damschroder et al 2009). In addition, Normalisation Process Theory (Murray et al 2010) will inform our analysis of the potential for future integration ('normalisation') of this model of care into routine maternity practice within the NHS

Risks associated with study procedures

There are no anticipated risks to participants. However as in all interventions, there may be unanticipated risks.

The feasibility work and pilot trial have provided the opportunity to address some emergent risks and develop and test interventions to address these. The learning has fed into the processes of the full trial. Despite this, possible risks remain, particularly given the relative scale of the full trial. We will aim to minimize these with careful planning, monitoring, liaison with Trust personnel and appropriate interventions. Potential risks include:

1. The burden of data collection on participants. We have carried out extensive PPI work with respect to our data collection tools and implemented suggestions around length,

complexity, design, language. These have now been extensively tested in the pilot study and refined. We are aware that some of the questionnaire items are sensitive and could potentially cause distress (though this did not emerge from the pilot study). We will minimise the risk of any distress by ensuring research staff are experienced at conducting research of this nature and conduct all the fieldwork with appropriate sensitivity. Participants are made aware of the various routes for contacting the research team or local midwives via study information leaflets. We hope that the £10 vouchers participants receive will be a satisfactory 'thank you' for the effort participants make. Staff participating in the process evaluation will be made aware that they are not obliged to consent to taking part in observations or interviews and that the data they provided will be subjected to strict confidentiality processes.

2. Non-attendance for antenatal care. For example, some women assigned to group antenatal care may dislike the group element and not attend (despite being informed they are free to change their pathway at any time). Some women assigned to the control group may be disappointed not to be assigned to the Pregnancy Circles, or not understand their allocation to standard care, and possibly attend fewer antenatal appointments for this reason. Standard operating procedures will be in place (which include information about adverse events and serious adverse events processes – see below) to ensure that communication processes between the research team and participants are such that all women receive and understand the requirements of the trial arm allocation and that midwives and/or the research team note absences and immediately follow up individually to ensure that women do not miss out on their antenatal care. We make it very clear in our consent processes that women can choose to opt out of the intervention arm should they wish to, at any time, and receive standard care instead.

3. A [significant] breach in confidentiality. This is a risk in any research study. All staff on the REACH study are highly trained in terms of confidential practice. We have ensured that we have set up robust data security systems, in conjunction with our PCTU colleagues that all research staff will adhere to.

4. Inappropriate contact about the research with a woman who has lost her pregnancy following consent to participate. The research team will check with maternity services staff before participants, or potential participants, are contacted for study purposes, such as sending out follow up questionnaires. Our electronic questionnaire dispatch systems will include a 'yes/no' question for those operating them, on whether this check has been carried out.

5. Problems with providing adequate language support such that the understanding of women who don't speak English is put at risk. Our approach in the pilot, to aim to provide face to face support with back up from language line if necessary, was successful. We found NHS trust in house language support teams were generally able to provide support for recruitment, baseline questionnaire completion and consent. Support for other tasks, such as outcomes questionnaire completion, interviews and language support in the Pregnancy Circles, was often beyond the capacity of the in-house service but could be provided effectively by external privately-run interpreting agencies. We will liaise with local language support experts/services in the various study sites to ensure we have effective support in every site. We have the capacity to provide face to face support for data collection, in a place of a participant’s choice, in order to minimise any inconvenience/distress resulting from data collection.

6. Inadequate levels of management support affecting, for example, ability to adequately equip/train midwives with the necessary skills and support and/or inflexible service organisational structures inhibiting implementation of the intervention. The pilot study has clarified the support/flexibility required from the service, and allowed assessment of any added challenges when the intervention is tested on the scale required in the trial.

Managers will be made fully aware of these requirements at the point of signing up as a research site.

7. Wide diversity in how services are organized across the different sites, for example different arrangements for how and when booking appointments are arranged. We will work closely with local staff to ensure that local contexts are taken into account when planning research and intervention processes to ensure that patient and staff participants are not inconvenienced by the research.

8. Inadequate levels of management support affecting, for example, ability to adequately equip/train midwives with the necessary skills and support and significant competing service demands/priorities. We have undertaken a rigorous process of providing information to sites during the sign up process to ensure they can meet the requirements of the research.

9. Lower than anticipated recruitment rates in 1 or more sites. Our pilot demonstrated that it is feasible to recruit the required number of women within appropriate timescales (i.e. 4 weeks for each Pregnancy Circle). If this does not prove the case in any site, or a number of participants miscarry following consent, there will still be time to 'top up' the recruitment, reassess the geographical area being recruited from, address barriers and carry out the required communications with participants, before the Pregnancy Circle starts.

10. Potential contamination of the control group. It is possible that midwives delivering the intervention will change their practice in a standard care context as well as in the Pregnancy Circles, for example in terms of being more 'woman-led' and partnership orientated as result of the additional training and focus on these approaches in the model. The potential for such contamination of the control arm will be limited by the fact that several key elements of the Pregnancy Circles model cannot be reproduced in a standard care setting (e.g. the social element, the self-checking, the extended time of appointments, the degree of continuity of carer). However, there remains a risk which we will aim to minimise by requesting that midwives, who are facilitating the Pregnancy Circles do not deliver standard care appointments for control arm participants for the duration of the intervention delivery phase of the study, wherever possible. Service managers will be asked to support this principle where they can, for example when drawing up staff rosters. We realise that in some service settings, for organisational and resource reasons, this may be very difficult. For example, a Pregnancy Circles trained midwife may be required to staff an antenatal clinic where a control group participant has an appointment (as demonstrated by the study sticker on the patient's hand-held notes). There may be no other midwives available to provide this woman's care and so the Pregnancy Circles midwife will have to conduct the appointment. We will monitor potential contamination by asking the midwives delivering the intervention, via the feedback forms completed after each Pregnancy Circle, if they have been aware of providing care to any control group participants since the previous Circle, and if so to how many. We will also consider making 'relative risk of contamination' (as per the ways in which local maternity services are delivered) one of the criteria for the purposive selection of case study sites in the process evaluation and include this issue in the interviews with midwives delivering the intervention. This process data will allow us to assess relative levels, and potential effects, of contamination.

End of Study Definition

The end of the study is when the 2nd outcomes questionnaire data (3 months postpartum) has been collected and analysed and the final report completed.

8. STATISTICAL CONSIDERATIONS

Sample size

In terms of the primary outcome, to detect an increase in the proportion of babies born "healthy" by 8% between the control and intervention arm, with 90% power and a 5% significance level would require at least 866 women per arm (1732 total). This assumes an outcome proportion of 69% in the control arm and 77% in the intervention arm. This calculation also accounts for clustering within the intervention arm, with an intra-cluster correlation coefficient (ICC) of 0.05 (in the intervention arm), mean group sizes of 8 with cluster size variability assuming a Poisson distribution for cluster size and assumes 10% drop-out in both arms. To determine the power to detect changes in our former primary outcome, spontaneous vaginal birth, the total sample size of 1732 (for the new primary outcome) was used with the same clustering and drop-out parameters. When detecting a 7.3% increase in spontaneous vaginal birth from 70.2% to 77.5% and 5% significance, a power for SVB of 84.8% was calculated. Therefore, the study sample size of 1732 women (866 per arm) is sufficiently powered to detect changes in both the primary outcome (healthy baby) and also SVB (now a secondary outcome).

Method of Analysis

A statistical analysis plan will be written and signed off before any allocation codes are provided to the statistician analysing the trial. The analysis plan will be reviewed by the independent statistician on the steering committee. The randomisation stratification factors will be used as covariates in the models for the between treatment analysis. If models are to be adjusted for other covariates then these will be clearly stated in the statistical analysis plan.

The primary outcome of 'Healthy Baby' will be analysed using a logistic random effects model with a random intercept estimating a cluster specific effect in both arms, whereby in the intervention arm within Pregnancy Circle correlation will be accounted for and in the control arm each participant will be modelled as a cluster of size 1. We will conduct a complete case analysis, with women being analysed according to the treatment arm they were randomised to. We will present an odds ratio and associated 95% confidence interval. Secondary outcomes will be analysed using the same mixed effects model accounting for Pregnancy Circle correlation in the intervention arm and will be presented with appropriate treatment effect estimates (odds ratios, mean differences) and associated 95% confidence intervals. Any sensitivity and subgroup analyses will be defined in the analysis plan.

9. ECONOMIC EVALUATION

We will calculate the cost-effectiveness of Pregnancy Circles compared to control from conception until three months postpartum from a health and social cost perspective. A health economics analysis plan will be written and signed off before allocation codes are provided to the health economist. Group antenatal care has potential health implications and costs for both the mother and infant, in particular as a key aim of group antenatal care is better engagement of women with maternity and other health care services. This could potentially increase some service costs in the short term, but also improve the health and wellbeing of the infant and mother in the immediate period, and also in the medium and longer terms. Increasing the proportion of infants vaccinated is the most straightforward example of improved engagement with health care services. The cost of the intervention will include the cost of training and the cost of the pregnancy circles, the later calculated based on CRFs completed by midwives on the duration of the Pregnancy circles, the number of women in each circle and any additional time required in the set up and running of the circle. Inpatient antenatal care and postnatal care will be collected from patient records in both trial arms. Participants will also provide information on additional maternity and infant related

resource use via participant completed questionnaires at 35 weeks, post-partum and 3 months post-partum. Resource use will be costed based on published sources. We will report descriptive statistics for resources. Differences in costs between the two groups will be calculated using linear regression, adjusting for randomisation stratification factors as covariates and a random intercept for pregnancy circle. 95% confidence intervals will be calculated from bootstrapped results with bias correction.

NICE recommend that cost-effectiveness is calculated as the cost per quality adjusted life year (QALY) gained [39]. This methodology presents significant challenges for this study. Although measuring QALYs for the mother is possible; when and how to start measuring QALYs from the perspective of the infant is controversial and methodologically challenging. The EQ-5D has been included though to allow the calculation of QALYs in the mother, which will be calculated as the area under the curve adjusting for baseline and randomisation stratification factors with random intercept for pregnancy circle. 95% confidence intervals will be calculated from bootstrapped results with bias correction.

In the pilot trial, the economic evaluation explored alternative utility measures via the participant questionnaires. Additionally, we involved women in defining what a 'positive and healthy pregnancy and birth' is, so that we will be able to calculate the incremental cost per additional healthy birth for group antenatal care compared to control, using this composite measure. We have conceptualised a 'positive and healthy pregnancy and birth' as occurring if:

1. Mother is healthy
2. Baby is healthy
3. Felt they are provided with the help and advice she needs during and after pregnancy
4. Felt they have support from family, close others and/or health care services during her pregnancy, labour and when looking after their new-born(s)
5. Felt they had choice in their care
6. Felt they had good continuity of care from a midwife or other clinical professional.
7. Felt confident in feeding their infant

We are using the data collected at follow up in the pilot to assess the validity of this composite measure and to develop algorithms for how births might be classified on a continuum from 'healthy' to 'unhealthy'. (This work is currently on-going, and will be available for use in the full trial).

We will report the mean incremental cost per "healthy birth" and the mean incremental cost per QALY. Cost-effectiveness acceptability curves and cost-effectiveness planes will be constructed based on bootstrapped data as described above. Trial missing and censored data will be handled the same way in the economic evaluation as for the statistical analysis.

10. ETHICS

We have secured NRES approval for the study (ref 17/LO/1596). In seeking approval for the proposed study, we considered potential risks as described above.
Site-specific assessment will then be undertaken by the NHS R&D offices at the participating NHS Trusts as part of the research governance review.

Informed written consent will be obtained for participation in the trial. The right to refuse participation without giving reasons will be respected. Participants will remain free to withdraw

at any time from the intervention without giving reasons. If a participant withdraws consent from further study participation their data will remain on file to be included in the final study analysis unless the participant specifically requests to withdraw their information. If they request that their data be withdrawn it will not be included in the analysis and all direct identifiers will be destroyed. The data of women who miscarry will not be included in the analysis, as requested by the REC (favourable opinion received 28/04/18).

11. DATA HANDLING AND RECORD KEEPING

Information related to participants will be kept confidential and managed in accordance with the Data Protection Act, NHS Caldecott Principles, The Research Governance Framework for Health and Social Care, and the conditions of Research Ethics Committee Approval.

Participant survey data

Baseline questionnaires will be completed on paper. Some participants will complete electronic versions of the follow up questionnaires directly onto the REDCap database (via a survey link in an email). Others will complete paper versions. REDCap is a secure web-based tool that requires researchers accessing it to use a two-step verification process to gain access. The REDCap database will be developed, supported and securely hosted by the PCTU. Completed baseline questionnaires will be sent from research sites to the central research team using secure (tracked and signed for) postal routes. The completed paper versions of the questionnaires will be stored securely at UEL in a locked filing cabinet, in a locked office, that only members of the research team will have access to. Questionnaires are identified by participant ID number only and will be stored separately from any paperwork with identifiable information on, including consent forms. Data from paper questionnaires will then be entered, by the research team, onto the REDCap database.

Routine patient data

All electronic routine patient data will be electronically transferred from the participating trusts directly into the PCTU's safe haven using secure methods. Data will be transferred as per the PCTU's dedicated Secure File Transfer Protocol (SFTP service). All audio-recordings and transcripts will be stored securely as described above for the paper questionnaires. Transcripts will be pseudonymised when they are produced such that they do not contain participants' names or any other direct identifiers. Transcribers will be bound by a confidentiality agreement.

The tools and processes used to manage data have all been tested and amended as appropriate during the pilot.

Process evaluation data

Information about the process evaluation participants (both trial participants and staff) (e.g. name, contact details, demographic details) will be stored on databases on the secure servers at City, University of London (City) and University of East London (UEL). The information on staff will also be stored on secure servers at UEL, as UEL will be carrying out the monitoring of intervention delivery. The participant trial ID number will be used on collected data to ensure anonymity; ID numbers will also be generated for staff participating in the process evaluation. Signed consent forms will be stored separately in a locked filing cabinets in the offices of the research teams at City and UEL, which both require an access code to enter. Audio recordings of the research interviews will be downloaded to the secure servers at City, University of London or UEL and then deleted from the recording device. The interviews will be transcribed verbatim and confidentiality of personal data will be ensured through the use of anonymisation and pseudonymisation techniques. Each transcript will have a unique number which will correspond to an audio-recording. The transcribed data will be stored on the secure servers at City, University of London and UEL.

Post-trial data storage

Paper data

At UEL any paper-based data will be digitized (mainly using REDCap) by the research team during the study. Once analysis is complete all superfluous paper data will be shredded.

Any remaining paper-based data will be stored for 20 years and kept in a locked filing cabinet in the office of the research team at UEL, which requires an access code to enter.

City University advises researchers to keep their data for; the completion of their project + 10 years. Any paper data that has not been digitised will be stored in a secure locked store room.

Electronic data

UEL

At the end of the study all data collected (including that on REDCap) will be securely transferred from the PCTU to UEL.

Data, both qualitative and quantitative, that is suitable for open sharing will be stored (along with relevant metadata and documentation) in the UEL data repository, data.uel, without any restrictions (Open Data). This data will be thoroughly reviewed to ensure that it is truly anonymous, so that no security will be required. For instance, data relating to birthdates (for mother and child, as well as rare events – such as multiple births) will not be included in the dataset. This data will be reviewed every 5 years in accordance with UEL Research Data Management policy (http://www.uel.ac.uk/wwwmedia/services/library/lls/resources/rspresearchtools/Research-Data-Management-policy-for-UEL-FINAL.pdf). The data will be kept for the standard retention period of 20 years for clinical trial data.

Data that is not suitable for sharing will be securely stored in UEL's Arkivum data archive. Data is encrypted and only project personnel and UEL Admin staff will have access to it. This security will be handled by UEL IT by restricting folder access.

A metadata only record will be added to data.uel, to allow a record to be kept of data that has been created at UEL. There will be the same 5-year review which will look at whether the data should be retained. In both cases, the destruction would involve secure erasing of the data in consultation with UEL IT. The appraisal of the data after five years will be undertaken by the PI on the study (Professor Angela Harden).

City

As with paper data, data at City will be kept for 10 years in folders labelled with the name of the study / Principal Investigator / destroy date (DD). Any identifiable electronic data will be encrypted. At the end of the study these folders are transferred to the City IT team for save storage.

12. PRODUCTS, DEVICES, TECHNIQUES AND TOOLS

Techniques and interventions

Various materials and tools developed for use within the pilot trial of Pregnancy Circles will be amended and utilized in this trial. It is possible that some of these may constitute intellectual property (IP). We will work closely with our Technology Transfer Office (TTO), Queen Mary Innovation, to ensure that this is protected appropriately. Any IP developed will be held in Barts Health NHS Trust, with a collaboration agreement put in place to grant a licence back to the collaborators for the use of the foreground IP, as well as any terms around revenue sharing. We will work with Queen Mary Innovation TTO to develop a fully worked up IP strategy to ensure that any new IP is protected appropriately. Queen Mary Innovation will discuss all the IP issues with the relevant collaborating institutions' TTOs.

13. SAFETY REPORTING

The CI (AH) will send the Annual Progress Report to the main REC using the NRES template and to the sponsor.

AH will ensure that safety monitoring and reporting is conducted in accordance with the sponsor's requirements. Guidance documents for AEs and SAEs have been provided by the research team in order that staff (at NHS Trust level) are aware of their responsibilities for reporting any such events to the research team. All AE and SAEs will be recorded on a paper CRF which will be scanned and emailed for entry onto REDCap by central research team staff. A copy will be stored in the site file and the participant will be followed up by the research team. The AE/SAE will be documented in the participants' medical notes (where appropriate). AE/SAEs will be verified periodically by a designated clinician to confirm correct details and processes.

Serious adverse event (SAE):

A SAE occurring to a research participant will be reported to the main REC where in the opinion of the Chief Investigator the event was:

- Related – that is, it resulted from administration of any of the research procedures, and
- Unexpected – that is, the type of event is not listed in the protocol as an expected occurrence.

Where the CI considers a reported SAE is 'related' to the intervention and 'unexpected' she will report this to the sponsor within 24 hours of learning of the event and to the Main REC within 15 days in line with the required timeframe. Further guidance on this matter, is available on the NRES website and in sponsor guidance documents.

Types of SAEs listed on the study SAE form are:

Mother (i.e. participant)
Death
Life-threatening
Persistent or significant disability or incapacity
Hospitalization for duration of 4 or more nights
Any other safety issues considered medically important including those affecting participant's baby e.g. stillbirth/neonatal death, congenital anomaly or birth defect

It is standard practice on maternity trials to exclude as SAEs common events in pregnancy that are unlikely to be related to any research procedures. This is particularly relevant in trials of interventions, such as this one, which have a low risk profile. In order to maximise identifying actual signals for safety concerns for participants, hospitalisation is now only considered an SAE where the duration is for 4 or more nights, for any reason. Hospitalisation for day care is no longer considered an AE. Short stays (day and overnight) in hospital are relatively common in pregnancy and are unlikely to signal a safety concern. A requirement to report these creates an un-necessary burden and distraction for site staff. Where a shorter stay does appear to be for a serious event then it should be reported as '*any other safety issues considered medically important'*.

The main 'event' that will be reported as an AE is miscarriage (i.e. pregnancy loss before 24 completed weeks of pregnancy). It is unlikely that there will now be other AEs in a trial of this

nature; but our procedures allow for reporting should staff have concerns about potential AEs.

Urgent Safety Measures

The CI may take urgent safety measures to ensure the safety and protection of the trial subjects from any immediate hazard to their health and safety. The measures should be taken immediately. In this instance, the approval of the REC prior to implementing these safety measures is not required. However, it is the responsibility of the CI to inform the sponsor and Main Research Ethics Committee (via telephone) of this event immediately.

The CI has an obligation to inform both the REC in writing within 3 days, in the form of a substantial amendment. The sponsor (University of East London) must be sent a copy of the correspondence with regards to this matter. For further guidance on this matter, please refer to HRA website and sponsor SOPs.

14. MONITORING & AUDITING

The PCTU quality assurance (QA) manager has conducted a study risk assessment in collaboration with the CI. Based on the risk assessment, an appropriate study monitoring and auditing plan has been produced according to PCTU SOPs and authorised by the sponsor. The PCTU QA manager and the CI will agree any changes to the monitoring plan.

This study is one part of a wider programme grant. The trial will be monitored by both the overall Programme Steering committee as well as its own trial steering committee:

- **Programme Steering committee** – This group meets face to face at least once a year and will be responsible for: overseeing the whole programme grant (of which this trial is one component); monitoring progress of the constituent parts of the programme; ensuring scientific quality and clinical relevance; and adherence to ethics and research governance. All key programme grant collaborators will attend namely Professor Angela Harden, Dr Bethan Hatherall, Professor Christine McCourt, Ms Meg Wiggins, Professor Sandra Eldridge, and Miss Rachael Hunter. A range of independent experts who are not directly involved in the programme grant, will sit on this committee. These include: Professor Pat Hoddinott (Chair in Primary Care at Stirling University, with a particular interest in maternal and infant health) to chair the group and Oliver Rivero-Arias (health economist at the NPEU at Oxford University), Dr Liz Allen (medical statistician at the London School of Hygiene and Tropical Medicine, who specialises in the design and analysis of cluster randomised controlled trials), Kathryn Gutteridge (Consultant Midwife at Sandwell and West Birmingham NHS Trust) and Jenny McTiernan (PPI representative) as independent members.

- **Trial Steering Committee (TSC) and Data Monitoring Committee (DMC)** – This trial will also have its own Trial Steering Committee. This group will meet at least once per year during the trial period. This will be responsible for overseeing the trial, ensuring scientific quality and clinical relevance, and adherence to ethics and research governance. The CI, trial statistician, trial manager and lead research fellow will attend this committee, as well as at least three independent members with relevant expertise who are not directly involved in the trial. The independent members will include a chair with relevant expertise, a statistician and an economist. There will also be a PPI member. At its first meeting, the committee decided a separate DMC was not needed and approved arrangements for any necessary monitoring and reporting of interim data.

- **Trial Management Group** – this group, chaired by Professor Harden, will include lead co-investigators, researchers, and research midwives/local PIs dealing with the day-to-day running of the trial. It will meet monthly. This group will be responsible for overseeing the operational implementation of trial and will monitor progress and adherence to the protocol. The group will also monitor scientific quality and clinical relevance, and adherence to ethics and research governance and will act as appropriate to remedy any difficulties.

Patient and public involvement

Additional to the feasibility work already described involving local mothers (and informing the intervention and this protocol), the REACH Pregnancy programme has two lay co-investigators who have contributed to the development of the protocol, the participant information sheets, recruitment methods and data collection instruments. The City University Research 'Advisory Group for Maternal and Child Health Research' (which includes lay members of the public) and 'Katie's Team', the women's health research patient

and public advisory group for East London, have also been consulted about potential methods of recruitment.

The lay co-investigators will also be invited to contribute to data analysis and decisions relating to dissemination products and processes. There are also lay members on the Programme Steering Committee. There has been extensive prior public consultation in the local area regarding this study, including interviews and discussion and stakeholder group meetings.

The REACH Pregnancy Programme is a standard item on the Maternity Voice Partnerships (MVPs) Agendas for Waltham Forest, Tower Hamlets and Newham. Members of MVPs include NHS maternity staff and local representatives of maternity services users.

15. FINANCE AND FUNDING

The funder for the study is the National Institute for Health Research as part of a larger Programme Grant for Applied Research (RP-PG-1211-20015).

As the host organisation for the research and the intervention, Barts Health NHS Trust have committed funding for the intervention costs (identified as ‘excess treatment costs’ by the NIHR).

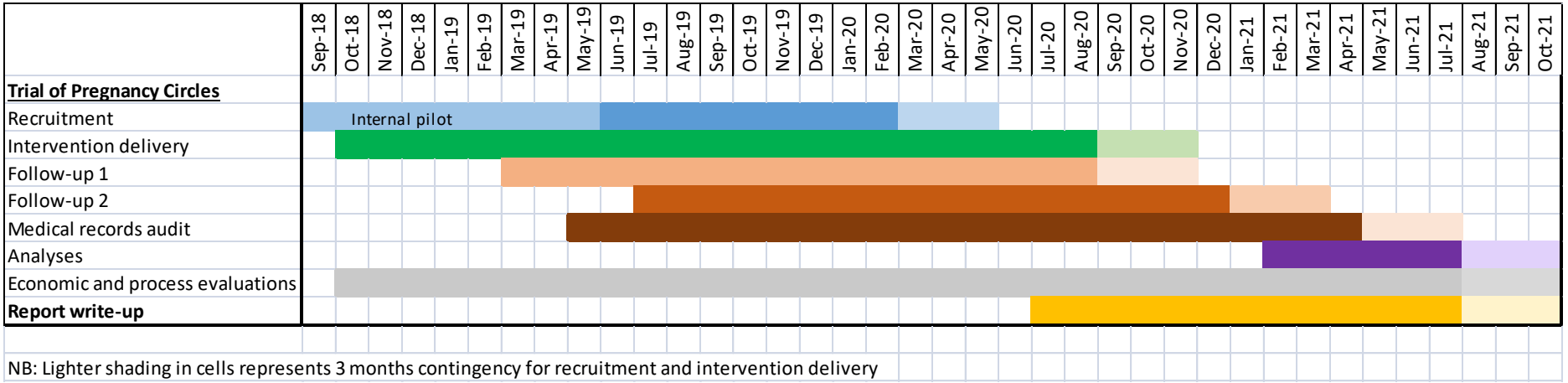
16. INDEMNITY

The study will be managed by the Chief Investigator, Professor Angela Harden (substantive employee of the University of East London, UEL). UEL indemnity insurance (covered by the UEL Clinical Trials Policy) will therefore apply.

17. DISSEMINATION OF RESEARCH FINDINGS

A publications policy for the study will be produced. The findings of this trial will be presented at national and international conferences (e.g. Royal Colleges of Midwives annual conference, the International Confederation of Midwives and relevant national and international public health conferences) and published in peer reviewed academic journals. Additionally, findings will be made available in accessible formats in newsletters for women, and in professional and practitioner journals. The findings will also be reported as briefing papers to healthcare commissioners and managers. We will use links with the Reproductive and Childbirth topic network to further disseminate throughout the NHS.

18. Timeline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Aug-21
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Oct-21
Trial of Pregnancy Circles
Recruitment
Internal pilot
Intervention delivery
Follow-up 1
Follow-up 2
Medical records audit
Analyses
Economic and process evaluations
Report write-up
NB: Lighter shading in cells represents 3 months contingency for recruitment and intervention delivery

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