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REACH Pregnancy Circles Trial

Submission date
22/10/2018

Recruitment status
No longer recruiting

Registration date
11/02/2019

Overall study status
Completed

Last Edited
23/07/2024

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is a randomised controlled trial (RCT) of a model of group antenatal care called Pregnancy Circles offered to women living in deprived and ethnically mixed parts of England. The trial aims to test the effectiveness of the group-based care. This RCT follows a pilot trial which tested feasibility of, and best methods for, the trial. Feasibility was demonstrated and lessons learnt have been incorporated in the trial protocol.

A Pregnancy Circle involves about 8 - 12 pregnant women, who live close to each other and are due to having their babies around the same time, having their antenatal care together in a community setting. The groups are facilitated by 2 midwives who combine clinical care with antenatal education and peer support. Care is organized in this way for the groups of women throughout their pregnancy and replaces standard antenatal care. There is good evidence from other settings that group antenatal care has a positive impact on women's experiences of antenatal services and may lead to better health outcomes.

Who can participate?
Women who are pregnant and registering for antenatal care with one of the maternity services taking part in the trial. Women can be expecting their first baby or already be a mother; they can be deemed "low" and "high" obstetric risk. Included women need to live within the working areas of the local midwife group facilitating a Pregnancy Circle 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.

What does the study involve?
Half the women taking part in the study will have Pregnancy Circle care; half will have usual antenatal care. The type of care a woman receives will be decided by a computer. This is called randomisation and means the two kinds of care can be compared. There is an equal chance of each type of care being the one received.

Anyone taking part will fill in a consent form and a questionnaire. This takes about 10-15 minutes. Randomisation then takes place straight away – unless a woman wants more time to think – in which case it can take place about a week later if a decision is made to take part. When a participant is about 8 months pregnant, and again when their baby is about 3 months old, they will be asked to fill in another short questionnaire by post or by email at home. Help can be

provided over the phone including with an interpreter, if required. Also, some information from hospital records, such as the baby's birth weight, will be collected by researchers. Participants may be invited to be interviewed by a researcher, when they have had their baby, about their experience of antenatal care. Also some antenatal care sessions may be observed by a researcher.

What are the possible benefits and risks of participating?
Benefits include helping us learn how we can provide better care for women in pregnancy. Also, participants will receive a £10 voucher for each of the 3 questionnaires as a thank you for the time involved. Interestingly we know that just taking part in research can be beneficial because of the positive effects that come from helping out in this way.

Disadvantages are the time required such as filling in the 3 questionnaires. Also some women may be disappointed if they don't get the type of care that they think they might prefer.

Where is the study run from?
City University of London (UK)

When is the study starting and how long is it expected to run for?
The study started in September 2018. It was expected to run for 2 years. The COVID-19 pandemic led to a pause in the trial. It will now complete in July 2024.

Who is funding the study?
The National Institute of Health Research (NIHR) (UK)

Who is the main contact?
The research team at Reach@city.ac.uk. or bethan.hatherall@city.ac.uk

Study website
https://blogs.city.ac.uk/reach/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
228894

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 35944; IRAS 228894

Study information

Scientific Title
REACH Pregnancy Circles: an individual-level randomised controlled trial of group antenatal care

Acronym
REACH

Study objectives
Does antenatal care provided via a model of group-based antenatal care (Pregnancy Circles) improve the health of babies and mothers compared with the standard individual model of antenatal care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/04/2018, London- Surrey Borders Research Ethics Committee (United Kingdom), ref: 17/LO/1596

Study design
Randomised; Both; Design type: Process of Care, Complex Intervention, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Effect of antenatal care on health of mothers and babies

Interventions
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 fully funded 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 (~ 16 weeks of pregnancy) that follows their antenatal booking appointment (which usually takes place between 10-12 weeks of pregnancy). 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. 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. Trust records will be checked by the facilitating midwives prior to making contact about the groups, to ensure pregnancy loss has not been recorded for any of the women. 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 will 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 (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 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 ('mat 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 mat 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 'mat 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 'mat' or 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.

Randomisation immediately follows consent and baseline questionnaire completion. Consent is carried out when a woman attends her booking appointment, or at her 12-week scan. Questionnaires are completed electronically using an electronic patient recorded outcome tool (REDCap) or on paper and participants receive a £ 10 voucher following completion.
Randomisation is carried out using an online system operated by the Pragmatic Clinical Trials Unit (PCTU). The randomisation system allocates participants to either Pregnancy Circles or usual care in a 1:1 ratio. The participant is told her allocation status face to face straight away (if recruited in person).
Women who want additional time to think about participation, following a face to face informed discussion, are given information to take home. 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 (either in paper form in the post, or electronically on REDCap). The participant will be informed of their trial arm status over the phone or by email and relevant information provided depending on allocation.
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.
Follow up is the same regardless of study arm. Participant outcomes data is collected in the trial via two routes: questionnaires completed by the participants at 35 weeks gestation and 12 weeks after the birth of the baby; routine maternity service data collected from the Trust at

approximately 1 month after the birth. The two outcomes questionnaires are 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 is emailed out to participants who indicated at recruitment that this is their preferred route; paper versions with reply envelopes and a link to the online version are sent to all other participants. All women are offered a £10 voucher for each of the two outcomes questionnaires they complete. These are posted to women on receipt of their completed questionnaire.
In advance of contacting women about these questionnaires, the research team check with facilitating midwives (intervention group) 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 works 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 after 2 weeks is sent a paper version in the post and, where an email address has been provided, via email. After a further 1 week if the questionnaire has not been returned, a researcher either emails or telephones to contact women to encourage completion.
The routine maternity data is accessed 1) through electronic patient records and 2) through an audit of paper maternity notes if missing data remains following 1).

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 01/12/2023:

A 'healthy baby' composite will be measured using data from maternity records at 1 month postpartum. The 'healthy baby' composite will consist of the following:
1. Live baby (i.e. no pregnancy loss before 24 completed weeks, not stillborn and no neonatal death within 28 days of delivery)
2. Born at term (37 weeks and above)
3. Appropriate weight for gestational age (GROW centile >99.99 & <90.1)
4. Not admitted to a neonatal intensive care unit (NICU) by which we mean:
Intensive Care Uni, SCBU, High Dependency Unit, but not transitional care

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Previous primary outcome measure as of 20/10/2020:

A 'healthy baby' composite will be measured using data from maternity records at 1 month postpartum. The 'healthy baby' composite will consist of the following:
1. Live baby (not stillborn and no neonatal death within 28 days of delivery)
2. Born at term (37 weeks and above)
3. Appropriate weight for gestational age (GROW centile >99.99 & <90.1)
4. Not admitted to a neonatal intensive care unit (NICU) by which we mean:
Intensive Care Uni, SCBU, High Dependency Unit, but not transitional care

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Previous primary outcome measure:

A 'healthy baby' composite will be measured using data from maternity records at 1 month postpartum. The 'healthy baby' composite will consist of the following:

1. Live baby (not stillborn and no neonatal death within 28 days of delivery)
2. Born at term (37 weeks and above)
3. Appropriate weight for gestational age (GROW centile >99.99 & <90.1)
4. Not admitted to a neonatal intensive care unit

Secondary outcome measures

Current secondary outcome measures as of 14/06/2024:
1. Spontaneous vaginal delivery (SVD), defined as a woman who delivers vaginally measured using data collected postpartum from maternity records
2. Women's empowerment measured using the Pregnancy-related empowerment scale (PRES) at 35 weeks of pregnancy (follow-up 1)
3. Women's satisfaction with maternity care, measured using the NHS Friends and Families test, collected at 35 weeks pregnancy (follow-up 1) and at three months postpartum (follow-up 2)
4. Breastfeeding initiation measured using data collected postpartum from maternity records
5. Mental well-being measured using the Short Warwick-Edinburgh Mental Wellbeing Scale at 35 weeks (follow-up 1) and 3 months postpartum (follow-up 2)
6. Live baby (i.e. no pregnancy loss before 24 completed weeks, no stillbirth after 24 completed weeks of pregnancy and no neonatal death within 28 days of the birth), measured postpartum from maternity records
7. Born at term (37 weeks + 0 days and above) measured postpartum from maternity records
8. Appropriate weight for gestational age (GROW centile >9.99 & <90.01) measured postpartum from maternity records
9. Not admitted to a neonatal care unit (which includes Intensive Care Unit, SCBU and High Dependency Unit, but NOT transitional care) measured postpartum from maternity records

Previous secondary outcome measures:
1. Women's empowerment is measured using the Pregnancy-related empowerment scale (PRES) at 35 weeks pregnancy (follow-up 1).
2. Spontaneous vaginal delivery, defined as 'Women whose labour starts spontaneously, progresses spontaneously without drugs, and who give birth spontaneously' is measured data collected postpartum from maternity records.
3. Women's satisfaction with maternity care is measured using the NHS Friends and Families test (follow up 1 and 2) and questions designed specifically for the study at three-months postpartum (follow-up 2)
4. Attendance at antenatal care is measured using data from maternity records at 1 month postpartum and at 35 weeks gestation (follow-up 1)
5. Social support is measured using the Duke Social Support Scale at baseline and three months postnatal (follow-up 2).
6. Self-efficacy is measured using the Pearlin Mastery Scale at baseline, 35-weeks pregnancy (follow-up 1) and three-months postnatal (follow-up 2).
7. Prenatal stress is measured using the Revised Prenatal Distress Questionnaire at baseline and 35-weeks pregnancy (follow-up 1).
8. Health service usage is measured at baseline, 35-weeks pregnancy (follow-up 1) and three-months postnatal (follow-up 2) through a self-report questionnaire of use over the previous four months.
9. Caesarean delivery (categorised as planned, emergency, or none) is collected postpartum from maternity records.
10. Infant birth weight (defined as low if less than 2500g) is collected postpartum from maternity records.
11. Place of birth is collected postpartum from maternity records.
12. Breast feeding initiation is collected postpartum from maternity records.

13. Breast feeding continuation and exclusivity is collected postpartum from maternity records.
14. Postnatal depression is measured using the Edinburgh Postnatal Depression Scale at three-months postpartum (follow-up 2).
15. Health-related quality of life is measured using EQ5D (at follow up 1 and 2)
16. Postnatal well -being is measured using the Checklist of Quality of Life from the National Maternity survey (at follow up 2

Overall study start date
01/08/2018

Completion date
12/07/2024

Eligibility

Key inclusion criteria
Patients:
1. Currently pregnant.
2. Registering for antenatal care with one of the included maternity services.
3. Live within the working areas of the local midwife group facilitators.
4. Estimated delivery date (as per last menstrual period assessment) that fits with those of a proposed group.

Midwife facilitators
1. Employed by the maternity services involved in the trial.
2. Attended study specific training provided by the research team or through a specialist MSc module at City, University of London ('Leadership and innovation in maternity care: facilitating successful groups and teams').

Participant type(s)
Mixed

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 2190

Total final enrolment
1907

Key exclusion criteria
Current exclusion criteria as of 20/10/2020:

Patients:
1. Under 16 years of age at the time of recruitment
2. Documented learning disability

3. Identified as being suitable for the ‘vulnerable women team’ - however 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)

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Previous exclusion criteria:

Patients:
1. Under 16 years of age at the time of recruitment
2. Documented learning disability
3. Identified as being suitable for the ‘vulnerable women team’

Date of first enrolment
10/09/2018

Date of final enrolment
13/06/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal London Hospital
Whitechapel Road
London
United Kingdom
E1 1BB

Study participating centre
Newham University Hospital
Glen Road
London
United Kingdom
E13 8SL

Study participating centre

Whipps Cross Hospital
Whipps Cross Road
London
United Kingdom
E11 1NR

Study participating centre
University Hospital Lewisham
Lewisham High St
London
United Kingdom
SE13 6LH

Study participating centre
Queen Elizabeth Hospital
Stadium Rd
Woolwich
London
United Kingdom
SE18 4QH

Study participating centre
Hemel Hempstead Hospital
Hillfield Rd
Hemel Hempstead
United Kingdom
HP2 4AD

Study participating centre
Whittington Hospital
Magdala Ave
London
United Kingdom
N19 5NF

Study participating centre
Royal Free Hospital
Royal Free London NHS Foundation Trust
Pond Street

London
United Kingdom
NW3 2QG

Study participating centre
Ashford and St Peters NHS Trust
St Peters Hospital
Guildford Road
Chertsey
United Kingdom
KT16 0PZ

Study participating centre
Princess Alexandra NHS Trust
Hamstel Road
Harlow
United Kingdom
CM20 1QX

Study participating centre
Basildon and Thurrock University Hospital
Nethermayne
Basildon
United Kingdom
SS16 5NL

Study participating centre
Worcester NHS Trust
Worcester
United Kingdom
DY11 6RJ

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre
Conquest Hospital
The Ridge
St. Leonards-on-sea
United Kingdom
TN37 7RD

Study participating centre
Colchester District General Hospital
Charter Way, Turner Road
Colchester
United Kingdom
CO4 5JL

Study participating centre
Ipswich Hospital
Heath Road
Ipswich
United Kingdom
IP4 5PD

Study participating centre
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
East Surrey Hospital
Canada Avenue
Redhill
United Kingdom
RH1 5RH

Sponsor information

Organisation

City, University of London

Sponsor details
School of Health and Psychological Sciences, Northampton Square
London
England
United Kingdom
EC1V 0HB

Sponsor type
University/education

Website
http://www.city.ac.uk

ROR
https://ror.org/04489at23

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan
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.

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing statement as of 28/04/2022:
Data, both qualitative and quantitative, that is suitable for open sharing will be stored (along with relevant metadata and documentation) in the City data repository 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 City Research Data Management policy (https://www.city.ac.uk/research/support/data). The data will be kept for the standard retention period of 20 years for clinical trial data.

The participant information sheet includes this information:
All information you give us will be stored securely and treated as confidential. It will be reviewed every 5 years and information not needed will be destroyed. The anonymous study data may be kept in a data archive for other researchers to use in the future

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

A metadata only record will be added to the City data repository, to allow a record to be kept of data that has been created at City. 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 City IT. The appraisal of the data after five years will be undertaken by the PI on the study (Professor Angela Harden).

Previous individual participant data (IPD) sharing statement:
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.

The participant information sheet includes this information:
All information you give us will be stored securely and treated as confidential. It will be reviewed every 5 years and information not needed will be destroyed. The anonymous study data may be kept in a data archive for other researchers to use in the future

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).

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		11/02/2019	11/02/2019	No	Yes
Protocol file	version V2.0	11/02/2019	11/02/2019	No	No
Protocol file	version V4.0	28/01/2020	18/02/2020	No	No
Protocol article	protocol	01/12/2020	23/10/2020	Yes	No
Protocol file	version 8.0	18/07/2022	29/07/2022	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Accessible version 5.0		01/12/2023	No	Yes
Protocol file	version 9.0	03/02/2023	01/12/2023	No	No
Protocol file	update to the published protocol	01/02/2024	05/03/2024	No	No
Protocol file		10/06/2024	14/06/2024	No	No
Protocol file	version 10.0	06/06/2024	14/06/2024	No	No
Statistical Analysis Plan	version 1.0	02/07/2024	02/07/2024	No	No