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REACH: Pregnancy circles pilot trial

Submission date
20/03/2017

Recruitment status
No longer recruiting

Registration date
03/04/2017

Overall study status
Completed

Last Edited
21/05/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Care during pregnancy (antenatal care) is important as it has the potential to improve women's health during and after pregnancy and also improve the health of the children they give birth to. Women from socially disadvantaged and ethnic minority groups often have difficulties with accessing antenatal care and report more negative experiences with care. This puts both them and their baby at risk of poorer health. Pregnancy circles is a new model of antenatal care. In Pregnancy Circles about 12 pregnant women, who live close to each other and are due to have their babies around the same time, have 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. A similar model of care has been used in other countries and settings (such as Australia and the USA, as well as in South London) and has been very popular, and shows good results. Four test groups (Pregnancy Circles) have recently been run in East London. Women and staff involved were very positive about the experience. There is now a need to carry out a large rigourous UK study of this kind of care. This pilot trial aims to find the best ways of testing the effectiveness of the group-based care to inform such a large study.

Who can participate?
Pregnant women living within the working areas of local midwife facilitators, who have a documented learning disability.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive usual antenatal care on a one-to-one basis with a midwife. Those in the second group receive all of their usual midwife-led antenatal care within a 'Pregnancy Circle'. This involves attending regular, two-hour long group sessions run by trained midwives. The first part of each session involves 'self-care activities' (e.g. women will be encouraged to take an active part in their 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 involve short one-to-one sessions with one of the midwife facilitators for individual health checks while the rest of the group has a group discussion facilitated by the second midwife. All participants are asked to complete three questionnaires during the study and data on service use and birth outcomes are accessed through patient records. Some participants are also invited to take part in interviews.

What are the possible benefits and risks of participating?
Women who take part benefit from receiving a £10 voucher for each of the three questionnaires they complete. There is a risk of women being disappointed if they are allocated to the group not receiving the group care. In addition, the questionnaires take time to complete.

Where is the study run from?
1. Royal London Hospital (UK)
2. Newham University Hospital (UK)
3. Whipps Cross Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2016 to January 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Ms Mary Sawtell
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Contact information

Type(s)
Public

Contact name
Ms Mary Sawtell

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 32160

Study information

Scientific Title
An individual-level randomised controlled pilot trial of group antenatal care

Acronym
REACH

Study objectives
The aim of this study is to find the best methods for testing the effectiveness of group antenatal care for pregnant women, to inform a possible later full trial of the model.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Service, 11/08/2016, ref: 16/NS/0090

Study design
Randomized; Both; Design type: Process of Care, Management of Care, Validation of outcome measures

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Reproductive health and childbirth, Primary sub-specialty: Other; UKCRC code/ Disease: Reproductive Health and Childbirth/ Delivery

Interventions
Pregnancy Circles are a bespoke model of antenatal care. Pregnancy Circles are being implemented by a London NHS Trust as part of its service development, initially on a small-scale basis. Each ‘Pregnancy Circle’ will consist of between 8 to 12 pregnant women who have estimated delivery dates within the same approximate two-week period. The women who consent to participation in the study will be randomly assigned to one of two arms of the trial.

One arm will receive standard antenatal i.e. 1:1 care from a midwife, whereas the other arm will receive all of their usual midwife-led antenatal care within a 'Pregnancy Circle'. Randomisation will be stratified by estimated delivery date and the location of the Pregnancy Circle.

Those women randomised to the group antenatal care will start attending the 'Pregnancy Circle' for the first time at the routine midwife appointment (approximately 16 weeks of pregnancy) that follows their antenatal booking appointment (which usually takes place between 8-12 weeks of pregnancy). Subsequently the women will continue to attend the Circle according to the normal antenatal care schedule. Any woman who chooses to discontinue her care in a group during pregnancy will transfer to the conventional care pathway. Any woman who must discontinue with the group due to pregnancy loss, will be able to contact their named midwife and be referred to medical services.

Each Pregnancy Circle group session will be facilitated by two midwives supplemented with bilingual health advocates or other support staff as appropriate. The same two midwives will facilitate all the sessions for a Pregnancy Circle. The women will receive standard postnatal care but will also be invited to a postnatal reunion group held approximately one month after the last antenatal appointment at approximately 40 weeks of pregnancy. A local health visitor (HV) will co-facilitate this reunion postnatal group with the midwives. Women in the control group will continue to have standard postnatal midwifery 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 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) while the rest of the group has a group discussion facilitated by the second midwife. 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 the individual health check or at the end of a session by a woman's lead midwife, whilst the other midwife continues facilitating the group. The content of group discussions will be woman-led, supplemented as appropriate by the facilitating midwives to ensure that essential topics are covered, as per national and local guidelines. 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 and format, but with a focus on maternal postnatal wellbeing and the wellbeing of the baby and infant feeding support.

Outcomes and economic data will be collected via questionnaires completed by the participants at three time points: baseline (at the point of recruitment); 35 weeks of pregnancy; four months postnatal. Trust routine maternity service data will also be collected, after the birth, for outcomes assessment and economic evaluation purposes and stakeholder interviews will provide insights into acceptability of research and intervention processes, including the use of interpreters to support women who do not speak English.

Intervention Type
Other

Primary outcome measure
1. Recruitment is measured using a proforma at recruitment and brief interviews with women, at recruitment, who decline participation
2. Uptake of care is measured using monitoring forms completed by the facilitating midwives at

the first 2 Pregnancy Circles
3. Retention is measured using monitoring forms completed by the facilitating midwives
4. Assessment response rates and completion is measured by response rates and completeness of data obtained at baseline, first follow up (35 weeks of pregnancy) and second follow up (4 months postnatal). Completeness of routine maternity data collected at 1 month postnatal from electronic compared with paper records will also be assessed.
5. Language support is measured via questionnaires at first and second follow up time points; by postnatal interviews with participants and by observations during intervention delivery

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/03/2016

Completion date
12/10/2019

Eligibility

Key inclusion criteria
1. Women aged 16 years of age and over at the time of recruitment
2. Currently pregnant and registering (or registered) for antenatal care at the participating NHS Trust maternity service, including both primiparous and multiparous women, and women deemed “low” and “high” risk
3. Live within the working areas of the local midwife group facilitators
4. Estimated delivery date that fits with those of a proposed group
4. Documented learning disability

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Female

Target number of participants
Planned Sample Size: 72; UK Sample Size: 72

Total final enrolment
74

Key exclusion criteria
1. Non-pregnant women
2. Women registered for antenatal care at other NHS services outside of Barts Health NHS Trust

3. Women who live away from the target areas
4. Women whose estimated delivery dates do not fit with the proposed group start date
5. Women who are under 16 years old
6. Women with a documented learning disability. When recruiting for specific groups, non-English speaking women who speak a language that is not a target language for that particular group.

Date of first enrolment
04/01/2017

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
Newham University Hospital
Gen Road
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E13 8SL

Study participating centre
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Sponsor type
University/education

ROR
https://ror.org/057jrqr44

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

1. Protocol paper submitted to 'Pilot and Feasibility Studies' (BMC)
2. The findings will be presented at national and international conferences (e.g. Royal Colleges of Midwives annual conference, the International Confederation of Midwives Congress and relevant national public health conferences) and published in high impact peer reviewed academic journals. Additionally, findings will be made available in accessible formats in newsletters and on the study website, as well as in professional and practitioner journals Intent to publish
3. The findings will also be reported as briefing papers to healthcare commissioners and managers and to service users via Maternity Service Liaison Committees. Links with the Reproductive and Childbirth topic network will be used to further disseminate throughout the NHS. Intent to publish

Intention to publish date
01/09/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ms Mary Sawtell (m.sawtell@ucl.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/11/2018		Yes	No
Results article		16/03/2023	20/03/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Qualitative study	24/09/2024	30/09/2024	Yes	No
Other publications	Improving diversity in recruitment	21/05/2025	21/05/2025	Yes	No