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POPPIE: Pilot study Of midwifery Practice in Preterm birth Including women's Experiences

Submission date
21/08/2017

Recruitment status
No longer recruiting

Registration date
21/08/2017

Overall study status
Completed

Last Edited
17/09/2024

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
In 2012, 7% of live births in England and Wales were premature (born before 37 weeks). Babies born prematurely may need special care, are more likely to die and are more likely to have disabilities or develop health problems in adult life than those born at full term. In 40% of cases, the cause of premature birth is unknown. However, it is known that some women are more at risk. This includes, for example, those who have previously given birth early, have had a late miscarriage or women who have had surgery on their cervix. A study found that women who receive care from the same midwife or team of midwives during pregnancy, birth and after birth are 24% less likely to experience preterm birth. Screening women at risk of preterm birth in specialist obstetric clinics is now considered to be helpful, but these methods are rarely used and women who require specialist expertise often suffer from fragmented maternity care. A care pathway has been developed which combines continuity of midwife care with rapid referral to a specialist obstetric clinic throughout pregnancy through to the postpartum period for women who at high risk of preterm birth. The aim of this study to test whether this new model of care is feasible and improves experience and outcomes for mother and child.

Who can participate?
Pregnant women with a single pregnancy (24 weeks or less) who at risk of preterm birth

What does the study involve?
Participants are randomly allocated either to standard care or the preterm midwifery team. Participants allocated to standard care receive the same care as they would normally receive according to their local maternity services in line with usual practice. Participants allocated to the the preterm midwifery team are assigned a named midwife and a partner midwife who together with a small team of midwives provide continuity of care throughout pregnancy, birth and the postnatal period. The midwife works in partnership with the participants, assesses their needs, plans their care, refers them to other professionals if required, and ensures that they have access to maternity services needed. All participants are followed up through the hospital records and questionnaires. Some participants are invited to attend an interview during the postnatal period about their experience of the type of care received.

What are the possible benefits and risks of participating?
It cannot be promised that the study will directly benefit the participants, but it will help to develop a model of maternity care that may benefit women in the future. Taking part in the study is not expected to disadvantage participants in any way. However, completing the questionnaires and an interview may take up to one hour of their time.

Where is the study run from?
Lewisham and Greenwich NHS Trust (UK)

When is the study starting and how long is it expected to run for?
May 2017 to May 2019

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

Who is the main contact?
1. Mrs Cristina Fernandez Turienzo
cristina.fernandez_turienzo@kcl.ac.uk
2. Prof. Jane Sandall
jane.sandall@kcl.ac.uk
3. Mrs Jackie Moulla

Study website
https://www.medscinet.net/poppie/

Contact information

Type(s)
Scientific

Contact name
Mrs Cristina Fernandez Turienzo

ORCID ID
http://orcid.org/0000-0002-7393-6593

Contact details
Department of Women and Children’s Health
School of Life Course Sciences
Faculty of Life Sciences & Medicine
King’s College London
St. Thomas' Hospital
London
United Kingdom
SE1 7EH
+44 (0)207 188 7188 (exte. 89853)
cristina.fernandez_turienzo@kcl.ac.uk

Type(s)
Scientific

Contact name
Prof Jane Sandall

ORCID ID
http://orcid.org/0000-0003-2000-743X

Contact details
Department of Women and Children’s Health
School of Life Course Sciences
Faculty of Life Sciences & Medicine
King’s College London
St. Thomas' Hospital
London
United Kingdom
SE1 7EH
+44 (0)20 7188 3639
jane.sandall@kcl.ac.uk

Type(s)
Scientific

Contact name
Mrs Jackie Moulla

Contact details
Lewisham and Greenwich NHS Trust
University Hospital Lewisham
Lewisham High Street
London
United Kingdom
SE13 6LH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
31951; 214196

Study information

Scientific Title
POPPIE: Pilot study Of midwifery Practice in Preterm birth Including women's Experiences

Acronym
POPPIE

Study objectives
A model of continuity of midwifery care for women at risk of preterm birth is feasible, and improves pregnancy experience and outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - South East Research Ethics Committee, 07/03/2017, ref: 17/LO/0029

Study design
Randomised; Interventional; Design type: Process of Care, Complex Intervention, Management of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
https://www.medscinet.net/poppie/patientinfo.aspx?lang=1

Health condition(s) or problem(s) studied
Specialty: Reproductive health and childbirth, Primary sub-specialty: General Obstetrics/ Midwifery; UKCRC code/ Disease: Reproductive Health and Childbirth/ Complications of labour and delivery

Interventions
The allocation ratio of intervention to control will be 1:1. Randomisation will be managed via a secure web-based randomisation facility hosted by MedSciNet which will write the randomisation program and hold the allocation code.

POPPIE care
Women randomised to the intervention group will receive continuity of midwifery care, which aims to provide ante-, intra- and postnatal care mainly from one midwife or her/his practice partner (backed up by the team for out of hours care) in either community or hospital settings, to a defined group of women identified at increased risk of preterm birth. Midwife continuity of care is provided in a multi-disciplinary network of consultation and referral with other care providers. Some antenatal and/or intrapartum and/or postpartum care is provided in consultation with medical staff as appropriate. Within these models, midwives are, however, in partnership with the woman, the lead professional with responsibility for assessment of her

needs, planning her care, referral to other professionals as appropriate, and for ensuring provision of maternity services. The POPPIE team will comprise 6 wte midwives, including the team leader.

Standard care
Women allocated to the control group will receive the current model of maternity care at the study site with access to expertise as required according to NICE and Trust antenatal care guidelines. Antenatal care is provided by antenatal staff (midwives and obstetricians). Staff in the Birth Units provide labour and birth care and midwives in the postnatal ward provide postnatal care. Women are also offered midwifery visits at home following discharge from hospital.

Intervention Type
Other

Primary outcome measure
The initiation of the following interventions related to the prevention and/or management of preterm labour and birth: antibiotics for UTIs, smoking cessation and domestic violence referrals, transvaginal scan assessments of the cervix, fetal fibronectin assessments, cerclage insertion, progesterone administration, corticosteroid administration, magnesium sulphate administration, admission for observation or in utero transfer; Timepoint(s): following birth

Secondary outcome measures
1. Recruitment and attrition rates and acceptability to women, healthcare professionals and stakeholders; Timepoints: at baseline/randomisation and in mid and post-implementation
2. Health in pregnancy: other complications; Timepoint: following birth
3. Labour and birth outcomes; Timepoint: following birth
4. Maternal and neonatal postnatal outcomes; Timepoint: following birth
5. Measure of implementation; Timepoints: early, mild and post-implementation
6. Measure of quality of care; Timepoint: 4/6 weeks after birth
7. Measure of women’s experience (trust, stress, system responsiveness, and safety); Timepoint: 4/6 weeks after birth
8. Assessment of psycho-social health; Timepoints: at baseline/randomisation and 4/6 weeks after birth
9. Health economic analysis of cost and resource use for mothers and infants; Timepoint: post-implementation

Overall study start date
01/05/2017

Completion date
30/05/2019

Eligibility

Key inclusion criteria
Asymptomatic pregnant women with singleton pregnancy and ≤ 24 weeks' gestation and identified at risk of PTB fulfilling one or more of the following criteria:
1. Cervical surgery (such as cone biopsy, LLETZ)
2. Uterine abnormality (such as bicornuate uterus)
3. Previous short cervix

4. Short cervix this pregnancy (< 25mm)
5. Previous cerclage
6. Previous premature ruptured membranes (< 37 weeks)
7. One or more previous PTB (< 37 weeks)
8. Previous late miscarriage/abortion (>14 weeks)
9. Smoking at booking

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 350; UK Sample Size: 350

Total final enrolment
334

Key exclusion criteria
1. > 24 weeks' gestation
2. Aged < 19 years old at recruitment
3. Unable/unwilling to give informed consent
4. Multiple pregnancy
5. Resides outside the catchment area covered by Lewisham Hospital
6. Receiving care from an specialist team already (e.g., teenagers, women suffering severe mental health illness, domestic violence or human trafficking; women with pre-existing diabetes, HIV, hepatitis)

Date of first enrolment
11/05/2017

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lewisham and Greenwich NHS Trust
Lewisham High Street
London

United Kingdom
SE13 6LH

Sponsor information

Organisation
King's College London

Sponsor details
King’s College London
James Clerk Maxwell Building
Waterloo Campus
57 Waterloo Road
London
England
United Kingdom
SE1 8WA

Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research CLAHRC South London

Results and Publications

Publication and dissemination plan
The trialists hope to submit the protocol soon for publication. The study protocol can also be accessed from the POPPIE website: https://www.medscinet.net/poppie/

The findings of the trial will be disseminated to the scientific and non-scientific community. The main results will be presented in a scientific conference and published in a peer reviewed journal. The plan is to submit the main results for publication within 2 months of the end of the trial.

Intention to publish date
30/10/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Feasibility results	06/10/2020	08/10/2020	Yes	No
Other publications	Process evaluation	12/01/2023	30/03/2023	Yes	No
Other publications	Participants' experiences		05/05/2023	Yes	No
Protocol article		14/05/2019	05/05/2023	Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 0.1	04/01/2018	17/09/2024	No	No