

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

<b>Submission date</b> 21/08/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 21/08/2017	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/09/2024	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> 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 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?

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2. Prof. Jane Sandall  
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3. Mrs Jackie Moulla

**Study website**

<https://www.medscinet.net/poppie/>

## Contact information

**Type(s)**

Scientific

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**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, mid 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  $\leq 24$  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 a 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

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## Sponsor information

### Organisation

King's College London

### Sponsor details

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### 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?
<a href="#">Results article</a>	Feasibility results	06/10/2020	08/10/2020	Yes	No
<a href="#">Other publications</a>	Process evaluation	12/01/2023	30/03/2023	Yes	No
<a href="#">Other publications</a>	Participants' experiences		05/05/2023	Yes	No
<a href="#">Protocol article</a>		14/05/2019	05/05/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Statistical Analysis Plan</a>	version 0.1	04/01/2018	17/09/2024	No	No