S1 Text: Data Analysis Plan

Data analysis plan (v 0.1)

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

IRAS Number 214196

Principal Investigator: Professor Jane Sandall

Trial statistician: Mr Paul T Seed

Researcher: Cristina Fernandez Turienzo

Version 0.1 4 Jan 2018

NHS National Institute for Health Research

Collaboration for Leadership in Applied Health Research and Care South London (CLAHRC South London)

KING'S College LONDON

Lewisham and Greenwich NHS NHS Trust

0 Status of draft

This is the first draft of the POPPIE data analysis plan, prepared prior to the TSC on 11 Jan 2018. It will be expanded by the inclusion of dummy tables following discussion, and in line with the variables being collected within the database. Dummy tables will include row and columns headings, indications of the analyses to be conducted and data to be presented, and relevant footnotes.

1 Introduction

The aim of the POPPIE pilot study is to assess the feasibility of a fully powered randomised controlled trial to address the question whether continuity of midwife care improves quality of care and outcomes in pregnant women at higher risk of preterm birth.

As such, we are interested primarily in the numbers of eligible women, the rate of recruitment, the proportion of women retained with complete outcome data, and the overall event rate for the primary outcome. Given these numbers, the power calculation can be revised appropriately, and a full study planned.

2 Methods of analysis

Recruitment rates will be presented as numbers recruited per month. Event rates will be presented as the proportion of women experiencing the event, both with 95% confidence intervals.

Comparisons between treatment groups will be according to the intention to treat principle, with each woman analysed according to the originally allocated treatment. For binary outcomes, results will be presented as risk ratios; with risk differences for the primary endpoint. For questionnaires, recommended methods of summary will be used. For other continuous variables, standard distributional checks will be carried out, and log or other transformations used if needed. To improve accuracy, adjustments will be made for baseline measurements of continuous variables where they have been collected. Missing baseline values will be replaced by the mean, with an appropriate dummy variable to represent missingness.

For continuous measures, means and SD will be given, by group, with mean differences and 95% confidence intervals. For events and other binary outcomes, results will be expressed as n (%), with risk ratios.

3 Process variables

These express the extent to which the planned complex intervention has been followed for each woman. Recruitment and attrition are often considered with process variables. In the pilot study, it is likely that there will not be enough information to accurately analyse the impact of process variables on the clinical outcomes.

We will investigate differences in the way the intervention was implemented, and see if these can be related to differences in outcome.

4 Broader Process evaluation

A broader process evaluation will use qualitative and quantitative data to examine:

- Assessment of recruitment, randomisation, treatment, and follow-up assessment process.

- Adoption (also referred to as uptake), acceptability to staff and women, fidelity to planned content and style of programme delivery, reach, penetration (integration of a practice within a specific setting) and sustainability (also referred to as maintenance or institutionalization) of different models of midwife continuity of care (12) (Table 1).
- Mechanism of impact on maternal physical, psychosocial, neonatal health, and women's experiences of care, quality of care and resource use.
- Wider contextual influences on programme implementation and outcomes and Impact of as perceived by local stakeholders.

Table 4.1 Summary of process variables

	Criteria
Recruitment	• % recruited no later than 24 weeks
	• % of participants meet eligibility criteria
	• % of eligible participants who are offered the programme are recruited
Attrition	% of participants who leave the programme and at what stage/why
Dose/Fidelity	Participants receive:
	• % of antenatal visits attended by named midwife/partner/ back up team midwife
	• % attendance by named midwife/partner/ back up team midwife during labour and birth.
	• % attendance by named midwife/partner/ back up team midwife for all community postnatal care.z<

5 Description of subjects

A simple table of baseline attributes will be presented with means and SD or n (%) as appropriate. Following best practice, no test will be made for differences between treatment groups at baseline.

Table 5.1 Description of subjects at start of trial

	Usual Care (n=)	Intervention (n=)
Gestation at recruitment (weeks)	Mean (SD)	Mean (SD)
Age	Mean (SD)	Mean (SD)
Ethnicity (UK census) White Black Asian Other	 N (%) N (%) N (%) N (%)	 N (%) N (%) N (%) N (%)
Other socio-demographics (e.g. income, employment, IMD, marital status)	N (%)	N (%)

Obstetric history		
Parity Primiparous	N (%)	N (%)
BMI	Mean (SD)	Mean (SD)
Pre-existing medical conditions (e.g. HTN, asthma)	N (%)	N (%)
Obstetric risk factors (e.g. previous preterm birth, PROM, cervical surgery)	N (%)	N (%)
Social risk factors (e.g. smoking, DV)	N (%)	N (%)

6 The primary outcome

We will also analyse the primary outcome, using standard methods to test for an effect of the intervention on quality of care. This is defined as the incidence of detection and management of possible preterm labour and birth; and assessed as the proportion of women in each arm receiving one or more appropriate primary interventions for preterm labour and birth: Antibiotics for UTIs, cerclage, progesterone, steroid administration, Magnesium Sulphate administration. An increase from 40% to 55% is considered both feasible and desirable.

As the primary outcome is a composite of several possible interventions, separate analyses will be presented for each of the components of the outcome, to show where any treatment effect occurs.

Table 6.1 Impact of intervention on the primary outcome and its components

	Usual Care (n=)	Intervention (n=)	Risk Ratio (95% CI)	P-value (for fully powered outcomes only)
Primary outcome				
Detection and management of possible preterm labour and birth	N(%)	N(%)	RR (95% CI)	0.xxx
Components of primary outcome (timing / appropriateness)				
Antibiotics for UTIs; transvaginal scans, FFT tests, cerclages, progesterone; corticosteroid; magnesium sulphate; admission for observation, IUT; smoking and DV referrals.	N(%)	N(%)	RR (95% CI)	

7 Additional outcomes

The following list of outcomes has not been powered for in designing the study. Results will be presented following a standard format, with appropriate comparison between treatment groups, as indicated in section 2 above. P-values will not be given, as these are unpowered comparisons, and significance tests could be liable to misinterpretation.

Separate tables of results will be given for each of the groups of outcomes indicated below:

- Health in pregnancy: other complications
- Labour and birth outcomes
- Maternal and neonatal postnatal outcomes
- Measure of implementation
- Measure of quality of care
- Measure of women's experience (trust, stress, system responsiveness, & safety)
- Assessment of psycho-social health
- Health and service use for mothers and infants
- Health economic analysis
- Assessment of recruitment, randomisation, treatment, and follow-up assessment process.

These will be assessed by a mixture of methods (postnatal survey with multiple validated scales and newly derived outcome variables, qualitative interviews with women, staff and stakeholders, cost-consequence economic analysis)