A pragmatic cluster population level randomised controlled trial of a community-level intervention to increase early uptake of antenatal care

Statistical Analysis Plan

Version: 1.0
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1. Administrative Information

Trial registration number: ISRCTN63066975

This SAP is based on **protocol version** 3.2 (date 01/08/2019)

SAP revision history

Protocol version	Updated SAP version no.	Section number changed	List of changes from previous version/protocol	Author of change	Date
2.0	0.2	-	Updated to match new SAP template	Lauren Greenberg	02/02/17
2.0	0.3		Updated to integrate the comments and update tables	Tahania Ahmed	07/12/17
3.1	0.4	All	Revision of analysis strategy and plan (all section)	Tom Hamborg	18/06/18
3.2	0.7	All		Tom Hamborg	25/11/22
3.2	0.8	3.1, 3.3, 5-7	Incorporated comments by independent statistician and added tables in Appendix	Tom Hamborg	18/12/22
3.2	0.9	3, 3.1, 3.2	Resolved queries on timing baseline and follow up cohorts	Angela Harden, Tom Hamborg	09/02/23
3.2	1.0		Sign off	Tom Hamborg	14/02/2023

*If the SAP has been published, indicate which version.

Members of the writing committee

Sandra Eldridge was responsible for the original statistical analysis strategy in the protocol. Lauren Greenberg has written the initial draft of the statistical analysis plan under the direction of Sandra Eldridge. Thomas Hamborg has written subsequent versions of the analysis plan (with input from the CI Angela Harden) and has primary responsibility for the analysis strategy.

Timing of SAP revisions in relation to unblinding of data/results

This document has been developed prior to examination of unblinded trial data by any of the people contributing. Blinded assessment of data has been undertaken and informed the analyses to be carried out. This examination was conducted to assess completeness and quality of the routinely collected data transferred by individual Trusts. The blinded data did not reveal which allocation group, cohort or ward participants belong to.

Remit of SAP

REACH is a NIHR funded programme grant. This SAP covers the analysis of the work package 1 trial (Community REACH). This plan is intended not to change or contradict the general aims of the protocol, but rather expand on them. In the event of a discrepancy the analyses described here will supersede those in earlier documents. The purpose of this document is to provide details of the statistical analyses and presentation of results of the effectiveness and mechanism evaluation analysis of the Community REACH trial. This SAP does not include in its remit the health economic analysis or the process evaluation. These analyses will be described in separate documents.

Analysis software

All analyses and data presentation described in this document and will be carried out using Stata version 17.0 unless otherwise specified.

Changes from planned analysis in the protocol version referenced above:

None

2. Background and trial design

Study objectives	• *The primary objective is to assess the effectiveness and cost-effectiveness of a community-based intervention for increasing early uptake of antenatal care. The primary outcome measure, assessed at ward level, is the proportion of pregnant women who have attended their antenatal booking appointment by the end of the 12th completed week of their pregnancy.* • *The secondary objectives are:* *(i) to investigate the impact of the community based intervention on a range of antenatal, maternity and infant outcomes. Secondary outcome measures will be antenatal admissions, emergency caesarean rates, preterm birth, low birth weight, breastfeeding at discharge, smoking rates and booking rates at 10 weeks gestation.* *(ii) To assess cost-effectiveness, intervention mechanisms and acceptability through integral economic and process evaluations.*
Study design	*Matched repeated cross-sectional cluster randomised superiority trial*
Setting	*NHS Trusts in North London and Essex providing maternity care. The unit of randomisation (cluster) is an electoral ward.*
Inclusion criteria	***NHS Trust level*** • *The NHS Trust is able to provide the routine maternity data required for randomisation and for assessment of outcomes.* ***Cluster level*** • *Electoral wards, served by the commissioned maternity care providers for Trusts enrolled on the study, where the proportion of women who have their first antenatal appointment by 12th completed week of pregnancy is below the NHS national target of 90%.* *AND* • *Wards where historically the majority of pregnant women have chosen to access the maternity services of the commissioned maternity care provider for the area in which they live, as opposed to services provided by another NHS trust.* *AND* • *Wards that are not neighbouring one another.* ***Individual level*** *All women who have a 'booking appointment' (first appointment with the maternity service) during the time frame of the study; live in one of the 20 wards selected for the study; and access their maternity care from the commissioned NHS providers for the local NHS trust.*

Interventions	*The novel community intervention in this study aims to raise awareness in the 10 intervention sites about: the purpose and value of antenatal care (ANC) early in pregnancy and how to access care. The research team have partnered with a local community organisation in each intervention site, who co-ordinate and manage the outreach delivery through a trained network of local, peer volunteers.* *The comparator is usual maternity care promotion and practice which will continue in electoral wards randomized to the control group*
Primary outcome measure(s)	*Proportion of pregnant women who have attended their antenatal booking appointment by the end of the 12th completed week of their pregnancy, assessed at ward level, for women who should have had their antenatal booking appointment 2-7 months after the intervention delivery commenced.*
Start date	*27th* March 2015
End Date	12th Oct 2019 (last cut-off date for births to be included in cohort 2 of any trust)
Study Duration	55 Months

3. Outcome measures

All outcomes are obtained from routinely collected NHS Trust maternity data. As this is a repeated cross-sectional study design outcomes are obtained from 3 different cohorts of women: cohort 1 (baseline) is prior to any intervention activities; cohort 2(FU1) is used to assess the treatment effect after the intervention start and cohort 3 (FU2) is used to assesses the sustained effect of the intervention after intervention implementation ends. . It would, in theory, be possible for a woman to be part of cohort 1 and 3 (with a subsequent pregnancy), however, these cases can't be identified from the available data and are likely to be rare.

3.1. Timing of outcome assessments

All outcomes are measured within three different time periods: Time points of certain trial related activities are used as anchors to define periods. Time point 0 is when the community training for delivery of the intervention begins. Time point 1 is the start of the intervention delivery. Time point 2 is the end of intervention delivery (6 months after time point 1). Wards are randomised in pairs. Time periods determining cohorts for control group wards are the same as for their paired intervention ward. A spreadsheet providing exact dates for all cohorts and defining time points will be provided as an appendix to the statistical analysis report.

Baseline: The baseline cohort consists of all pregnant women in a ward registered with participating Trust who would have had their antenatal booking appointment 8 months prior to Time point 0 to 3 months prior to Time point 0 had they booked by 12 weeks + 6 days of pregnancy. Data are extracted for all pregnant women with a registered booking appointment between 8 months prior to Time point 0 and 5 months after Time point 0. 5 months after Time point 0 is the latest a baseline cohort women could have had their booking appointment (see 3.2). Women who are 12 weeks + 6 days gestation after Time point 0 minus 3 months are subsequently removed.

FU1: The cohort of pregnant women who would have had their booking appointment between 1 month after the start of intervention delivery (Time point 1) and Time point 2 + 1 month had they booked by 12 weeks + 6 days of their pregnancy. Data are extracted for the period from Time point 1 plus 1 month to 13 months after Time point 1 and ineligible women removed as described for the Baseline cohort.

FU2: The cohort of pregnant women who would have had their booking appointment between Time point 2 + 1 month and Time point 2 + 7 months had they booked by 12 weeks + 6 days of their pregnancy. Data are extracted for the period from Time point 2 + 1 month to Time point 2 + 13 and ineligible women removed as described for the Baseline cohort.

3.2. Primary outcome

The primary outcome measure, assessed at electoral ward level, is the proportion of pregnant women who have attended their antenatal booking appointment by the end of the 12th completed week of their pregnancy (i.e. 12 weeks and 6 days of pregnancy) in cohort FU1. The outcome measure will be created as a binary variable from the 'Gestation at booking' variable transferred by Trusts. The day of a pregnant woman's first appearance in hospital is recorded as her booking appointment by Trust analysts. In some instances (e.g. birth) this attendance may not in fact have been a booking appointment. If gestation at booking is missing but variables Date of booking appointment, Date of Birth (of baby), and Gestation at birth are available then the binary primary outcome will be calculated and used where possible. The Date of Birth variable is available in month/year format so that there may be cases where it can't be definitely

determined whether the booking appointment took pace before or after 12 week + 6 days. In this case the variable will remain missing.

3.3. Secondary outcomes

The following outcomes are secondary outcomes for their measurements at FU1 and FU2:

1. Proportion of women who have attended their antenatal booking appointment by 10 weeks and 0 days of pregnancy
2. Number of antenatal hospital admissions (Defined as total number of hospital admissions during the whole length of the pregnancy (excluding delivery admission; HRG/NZ1 Codes)
3. Proportion of emergency caesarean sections – (an emergency caesarean section (C/S) is defined as a C/S that has to be carried out either earlier than a planned elective C/S or instead of a planned vaginal delivery due to complications). Categories "Emergency caesarean, Emergency LSCS, cat=4 are defined as 'yes'.
4. Proportion of pre-term births defined as births occurring before 37+0 weeks gestation
5. Proportion of babies with low birth weight defined as < 2.50kg
6. Proportion of women smoking at birth (yes/no)
8. Proportion of women who initiated breastfeeding (recorded as category in 'feeding method at discharge'; categories 'breastfeeding' and 'mixed breast and formula feeding' are converted into category 'yes')
9. Proportion of women who have attended their antenatal booking appointment by the end of the 12th completed week of their pregnancy (12 weeks + 6 days of pregnancy) in cohort FU2.

Women with multiple births will be excluded from the analysis of outcomes 3, 4 & 5. The method of calculating binary values of missing outcomes described in 3.2 will be used for secondary outcomes 1 & 9.

4. Study methods

4.1. Sample size calculation (from trial protocol v3.2)

In the Programme Development Grant research, we analysed routine data from the maternity service at Newham University Hospital, which contained the corresponding postcode for each pregnancy in Newham from the period April 2007-January 2011. We calculated by ward the variation in cluster size and the proportion accessing antenatal care by 12th week gestation as the basis for estimation of intra-cluster correlation coefficient and our sample size calculation. To detect an increase in antenatal booking by 12 weeks gestation from 73% to 80%, with 90% power at the 5% significance level requires at least 798 individuals in each group. To account for clustering (ICC = 0.005, mean cluster size 130, matching correlation = 0.3) requires nine clusters in the intervention group and in the control group.
Because this sample size is relatively small, and to guard against a substantial loss of power if a cluster is lost for any reason, we have added one cluster to each group. We will match pairs of clusters by hospital use by those in the ward seeking maternity care and by baseline rate of antenatal booking by 12 weeks. This will be measured per ward and will be collected pre-randomisation.

4.2. Randomisation procedure (from trial protocol v3.2)

Matched randomisation of the 10 pairs of wards with 1:1 ratio, is undertaken remotely by the Pragmatic Clinical Trials Unit (PCTU) at Queen Mary's University London (QMUL). The PCTU will inform the research team of the results of the allocation by secure email using a password protected file. Uscreates (the organisation who carried out initial co-deign activities to develop the intervention) and the site PIs are told the names of the 10 intervention wards.
Randomisation can be carried out sequentially at several time points, as Trusts are recruited. Wards are matched on the pattern of hospital usage by women seeking antenatal care and by the baseline rate of antenatal bookings by 12+6 weeks, categorised as very low (<70%) or low (71-89%). Matching criteria were determined using data from a 6-month period. Furthermore, wards are not permitted to neighbour one another to reduce the likelihood of contamination.

4.3. Blinding (from trial protocol v3.2)

It is likely that it will become known to stakeholders, in this case, maternity staff, where the intervention is running. Informatics staff in the participating Trusts will not be actively informed of the results of the randomisation. Maternity staff will be asked not to share this information with informatics staff that will be carrying out the data extraction for the study. Should 'unblinding' occur with these staff however we do not think this poses a significant risk as Trust staff have no specific involvement/investment in the intervention. Unblinding procedures are not applicable during this study.
Assessors conducting the analysis at the PCTU will be blinded to intervention allocation until the SAP has been signed off and the final dataset is extracted.

5. Analysis methods

5.1 Demographic characteristics

The following characteristics of women are collected at the booking appointment and will be summarised by treatment group as n (%) for categorical variables or proportions for binary variables for all three cohorts of women.

- Woman's age at booking (<20, 20-35, >35 years)
- Parity – number of times given birth (0, 1-2, >3)
- Ethnicity (as per census categories)
- Language spoken (English primary language – yes/no)
- Born in UK (yes/no)
- Deprivation quintile (1=least deprived, 5=most deprived; derived from post code)
- Proportion of women smoking at booking appointment (yes/no)
- Proportion of transferred in women– where booked at this hospital after 12+6 gestation (yes/no)
- Risk category (Standard/Intermediate/Intensive) The risk category is assigned to each woman based on a combination of medical and social risk by the maternity service

5.2 Adherence to treatment

This study assesses a novel community-level intervention relative to usual maternity care promotion where individual participant update cannot be measured. Participant adherence is therefore not applicable.

5.3 Information for the CONSORT flow diagram

A dummy flow diagram is provided in Appendix C.

5.4 General analysis principles

Analysis Population

The analysis will be on intention-to-treat (ITT) basis. All wards will be included in the analysis, and will be analysed according to the treatment group to which they were randomised. All participants on whom outcome data is available will be analysed, provided they were part of the cluster that was randomised (see section 7. Data cleaning). Participants were not able to withdraw consent for their data to be included in the analysis. A per-protocol population cannot be defined as participant adherence cannot be defined.

Missing Data

Analysis will be available case. The primary outcome 'gestation at booking appointment' was expected to be available for all participants by definition. A blinded assessment of primary outcome completeness identified < 2% missing data for the primary outcome. Following discussion with trusts, it was concluded that where data are missing this would be entirely due to Trust data recording policy or IT systems errors for the primary outcome and other gestation outcomes, i.e. not related to participant outcome values, and mostly due to Trust data recording policy or IT systems errors for other outcomes. Therefore no multiple imputation of missing data for the primary outcome analysis and main secondary outcome analyses will be carried out. Fixed value imputation sensitivity analyses are described in 5.7.

Some birth outcomes could be missing due to participant characteristics. For these outcomes we will therefore try to identify predictors of missingness using a logistic regression model with 'missing' as the outcome variable and in a sensitivity analysis impute data on an MAR basis for birth outcomes.

Information to be presented

For the analysis of the primary outcome and each secondary outcome we will present the following information:

- The number of participants included in each analysis, by treatment arm
- A summary statistic of the outcome (e.g. number (%)), by treatment arm
- The estimated treatment effect
- A 95% confidence interval for the estimated treatment effect
- A two-sided p-value

The treatment effect will be presented as odds ratio with its 95% confidence interval and associated p-value for the primary outcome and other binary variable outcome measures. Simple proportions will be presented as summary statistics by treatment arm. An appropriate risk difference between groups estimate will also be provided. All tests will be two-sided and will be considered statistically significant at the 5% level.

Adjustment for Matching Variables

Matching variables will not be included as covariates in analysis model as recommended by Thompson et al (1997). The matching correlation for the matching variable Baseline rate of antenatal booking will be estimated on the baseline cohort and reported.

Adjustment for Clustering

All analyses will account for clustering by ward. See section 5.5. for details.

Adjustment for Covariates

The main analysis of primary and secondary outcomes will not be adjusted for covariates. Secondary analyses will present adjusted estimates to assess consistency of treatment effect estimates.

5.5 Analysis of primary and secondary outcomes

The primary outcome will be analysed using a two-stage individual participant data meta-analysis technique for analysing paired CRTs. Each pair of wards is regarded an individual study in a meta-analysis for which the odds ratio estimated. These odds ratios are subsequently combined in the random effects model. Restricted maximum likelihood estimation (REML) will be used. The Hartung-Knapp modification to the DeSimonian-Laird estimator of the between study variance is used to construct t-based 95% confidence intervals for effect estimators.

Stata command:

ipdmetan , study(studyID) re(reml, hk) or : logistic outcome trt_grp

Should the above model fail to converge a standard DeSimonian-Laird estimator will be used.
Stata command:
ipdmetan , study(studyID) re(dl) or : logistic outcome trt_grp

Should this model also fail to converge a McNemar's test for paired proportions of the outcome at ward level will be used as the analysis model.

The risk difference will be estimated using the following command:
ipdmetan , study(studyID) re(reml, hk) : glm outcome i.trt_grp, family(binomial) link(identity)

All secondary outcomes apart from 'Number of antenatal hospital admissions' are binary variables and will be analysed using the same principles and analysis approach as the primary outcome. The use of the primary outcome model for count variables like 'Number of antenatal hospital admissions' has not been described in the literature. This outcome will therefore be analysed using a paired t-test on the mean number of admissions per ward.

5.6 Subgroup analyses

Sub group analysis will be performed on four pre-defined subgroup. It is recognized that the study will have limited power to detect differences at the sub group level, hence these analyses will be performed for hypothesis generation only. All subgroup analyses will be performed by estimating the treatment-covariate interaction within each pair of wards and pooling of the effect estimates thereafter.

Stata command:
ipdmetan , study(studyID) re(reml, HKSJ) or : logistic outcome trt_grp ## subgroup_var

Subgroups:

1. First time versus repeat pregnancy mothers(parity 0 vs >0)
2. Ethnicity category
3. Deprivation
4. Baseline rate of antenatal booking (<70% vs 70-89%).

5.7 Sensitivity and secondary analyses

1. Estimate the treatment effect leaving out any pairs of cluster in which the intervention was not fully delivered as intended (per protocol analysis)
2. Estimate the treatment effect of the primary outcome using a model adjusted for individual-level covariates IMD and ethnicity as fixed effects. Adjusted marginal proportion for treatment groups will be estimated using the approach by Norton et at (2013 (stata postestimation command: adjrr)
3. Imputation of missing primary outcome values. The following scenarios are considered:

a. Substitute all missing values of the outcome as having booked after 12 weeks + 6 days for both arms.
b. Substitute all missing values of the outcome as having booked after 12 weeks + 6 days in the intervention arm and before 12 weeks + 6 days in control arm wards. 'This is the most extreme imputation option and will provide a lower limit for potential effect estimates.
c. Substitute all missing values of the outcome as having booked before or after 12 weeks + 6 days with probability 0.5 in both arms.

5.8 Interim analyses

No interim analyses are in place.

5.9 Multiple testing

The type-I error rate for declaring statistical significance is α=0.05 throughout. No adjustment for multiple testing will be made. The number of secondary outcomes will be appropriately considered when presenting between group differences of secondary outcomes.

6. Other analyses, data summaries, and graphs

6.1 Other data analyses

Instrumental variable analysis to assess the mediation effect of implementation of the intervention.

The process evaluation showed that there were two distinct models of implementing the intervention denoted Model A and Model B. Model B is closer to the intended intervention model. An instrumental variable analysis will assess whether the treatment effect is mediated by the model type. This is conducted by estimating the local average treatment effect (complier average treatment effect) via two-stage least squares regression using ward-level summaries of the primary outcome and implementation model received (Agbla et al (2019)). In the first stage Model is regressed on treatment group. The second stage models the outcome variable on the predicted outcome received with Huber-White standard error correction. The stata command being used is *ivregress 2sls*

Should it not be possible to fit the above model, then the effect of the implementation model will be assessed by fitting an interaction term *Model x Treatment* group in the primary outcome model.

6.2 Safety analyses

There are no anticipated risks to study participants or to those involved with the intervention. Data is provided through routine monitoring at source in non-identifiable form and therefore collection of safety outcomes due to study participation is not possible. Maternal and infant deaths will be regarded as safety outcomes and will be presented number (%, CI) by treatment group per cohort.

6.3 Graphs

1. Forest plots showing the treatment effect for each pair of wards as will be produced for the primary outcome analysis, the primary outcome at FU2 and secondary outcomes at FU1
2. A figure showing the change over time (BL, FU1, FU2) of the primary outcome in terms of the estimated odds-ratio for all wards.

7. Data preparation and cleaning

All women *transferring in* after 12+6 weeks will be excluded from the analysis. If the variable *transferred in after 12+6 weeks* is missing then the participant will be retained.

Data were transferred as one dataset by each Trusts containing data potentially pertaining to more than one ward. The data will have to be merged and arranged by ward. A blinded assessment of transferred data revealed that coding of variable values by Trust data analysts deviated from instruction. A data cleaning appendix is being prepared showing all coding errors made in each transferred dataset and the rules for reformatting values to comply with instructions. Where mapping of transferred values to intended values was unclear or ambiguous the rule for reformatting will be decided by consensus by the trial team.

8. References

1. Thompson, S. G., Pyke, S. D. and Hardy, R. J. (1997), The design and analysis of paired cluster randomized trials: an application of meta-analysis techniques. Statist. Med., 16: 2063-2079.
2. Agbla, S. C., De Stavola, B. and DiazOrdaz, K. (2020) 'Estimating cluster-level local average treatment effects in cluster randomised trials with non-adherence', *Statistical Methods in Medical Research*, 29(3), pp. 911–933. doi: 10.1177/0962280219849613.
3. Norton, E. C., Miller, M. M., & Kleinman, L. C. (2013). Computing Adjusted Risk Ratios and Risk Differences in Stata. *The Stata Journal*, *13*(3), 492–509. https://doi.org/10.1177/1536867X1301300304

9. Appendices

Table 1 – Baseline characteristics

	BL		FU1		FU2	
	Intervention (n=)	**Control (n=)**	**Intervention (n=)**	**Control (n=)**	**Intervention (n=)**	**Control (n=)**
Women's age at booking N(%)						
<20						
20-35						
>35						
missing						
Parity at booking N(%)						
0						
1-2						
3+						
missing						
Ethnicity N(%)						
White British						
White (other)						
Asian						
Black						
Other						
missing						
English primary language N(%)						
Yes						
missing						
Deprivation quintile N(%)						
1-2						
3-4						
5-6						
7-8						
9-10						
ToC after 12wk+6d N(%)						
Yes						
missing						
Smoking at booking N(%)						
Yes						
missing						
Risk category N(%)						
Low risk						
Medium risk						
High risk						
missing						

Table 2 – Main results for primary and secondary outcomes at FU1

	Included in analysis		Summary measure		Treatment effect		
	Intervention N (%)	**Control N (%)**	**Intervention N (%)**	**Control N (%)**	**OR (95% CI)**	**OR p-value**	**RD (95% CI)**
Primary outcome							
Proportion of women having first antenatal appointment within 12wk + 6d							
Secondary outcomes							
Proportion of participants having first antenatal appointment within 10 wk+0d							
No of hospital admissions							
Pre-term births							
Proportion Emergency Caesareans section							
Low birth weight							
Smoking at birth							
Initiated breastfeeding							

Table 3 – Main results for primary and secondary outcomes at FU2

	Included in analysis		Summary measure		Treatment effect		
	Intervention N (%)	**Control N (%)**	**Intervention N (%)**	**Control N (%)**	**OR (95% CI)**	**OR p-value**	**RD (95% CI)**
Proportion of women having first antenatal appointment within 12wk + 6d							
Proportion of participants having first antenatal appointment within 10 wk+0d							
No of hospital admissions							
Pre-term births							
Proportion Emergency Caesareans section							
Low birth weight							
Smoking at birth							
Initiated breastfeeding							

Table 4: Subgroup analysis of primary outcome

	Intervention N(%)	Control N(%)	0dds ratio (95% CI)	p-value for interaction
Parity of mother				
0				n/a
1+				n/a
BL rate of booking				
<70%				n/a
>=70% and <90%				n/a
Ethnicity				
White British				n/a
White (other)				n/a
Asian				n/a
Black				n/a
Other				n/a
Deprivation quintile				
1-2				n/a
3-4				n/a

5-6				n/a
7-8				n/a
9-10				n/a

Table 5: Sensitivity analysis of primary outcome

	Included in analysis		Treatment effect		
	Intervention N (%)	**Control N (%)**	**OR (95% CI)**	**OR p-value**	**RD (95% CI)**
Analysis 1					
Analysis 2					
Analysis 3a					
Analysis 3b					
Analysis 3c					

Table 6: Mediation analysis of primary outcome

	effect (95% CI)	**SE**	**p-value**
Indirect effect (Trt -> mediator)			
Indirect effect (mediator -> outcome)			
Direct effect			
Total effect			

Table 7: Safety analysis

	BL		**FU1**		**FU2**	
	Intervention (n=…)	**Control (n=…)**	**Intervention (n=…)**	**Control (n=…)**	**Intervention (n=…)**	**Control (n=…)**
Maternal death N(%)						
Infant death N(%)						

Information for CONSORT flow diagram