ISRCTN63066975 https://doi.org/10.1186/ISRCTN63066975

Community intervention to increase early uptake of antenatal care

Submission date
06/05/2015

Recruitment status
No longer recruiting

Registration date
18/08/2015

Overall study status
Completed

Last Edited
30/12/2025

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
This study will look at the effectiveness of a community intervention programme to support women to have their first antenatal appointment with maternity services before the 13th week of pregnancy, in line with national guidelines. The study is part of a wider NIHR-funded programme of research that seeks to improve access to and experience of antenatal care for pregnant women living in socially deprived and ethnically diverse areas - the REACH Pregnancy Programme.

Who can participate?
Women who are pregnant/give birth during the time frame of the study and live in one of the 20 electoral wards in North and East London where women are more likely to delay the start of antenatal care.

What does the study involve?
We will randomly select 10 of the 20 wards as the ones where the community programme will take place. The programme will include: training a group of peer volunteers to promote antenatal care through local networks of women; development and distribution of campaign materials; and community events to promote key messages. We will work together with local communities to co-design and develop the content of the programme. We will analyse hospital data from local maternity services to see whether pregnant women living in the programme wards begin their antenatal care earlier, and see greater benefits for both themselves and their babies, than those living in the other 10 wards. We will look at whether the programme provides good value for money. We will also interview local people who help design and deliver the programme, in order to identify issues that supported or hindered its effectiveness within their communities. Finally, we will survey some pregnant women living in the study wards to see whether or not the programme influenced their decision about when to begin antenatal care.

What are the possible benefits and risks of participating?
The potential cost-effective benefits of increasing rates of early antenatal booking are improved health outcomes for women and children, through early identification of any health needs, uptake of time-specific screening tests, monitoring of the pregnancy, advice and support around healthy behaviour. The enhanced social support available from the community is also expected

to be beneficial. The intervention is also expected to benefit the members of the community recruited to design and deliver it. Benefits may include satisfaction gained from their role and acquisition of new knowledge and skills that may enhance employability. There are no anticipated risks to participants. However, as in all interventions, there may be unanticipated risks. It is possible given the intended 'reach' of the intervention into whole communities and not just women of child-bearing age that attempts to change service use behaviour may meet with resistance from some sections of the culturally diverse communities involved. This could create a dilemma for pregnant women who want to act on the message of the intervention but do not have support for this from their family/community. It is hoped that the co-design approach will minimise this risk.

Where is the study run from?
City, University of London (UK), (previously University of East London)

When is the study starting and how long is it expected to run for?
April 2015 to September 2023

Who is funding the study?
NIHR Programme Grants for Applied Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
167821

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
18723

Study information

Scientific Title
A pragmatic cluster population-level randomised controlled trial of a community-level intervention to increase early uptake of antenatal care (REACH Pregnancy Programme, Work Package 1)

Study objectives
This study will look at the effectiveness of a community intervention programme to support women to have their first antenatal appointment with maternity services before the 13th week of pregnancy, in line with national guidelines. The study is part of a wider NIHR-funded programme of research that seeks to improve access to and experience of antenatal care for pregnant women living in socially deprived and ethnically diverse areas - the REACH Pregnancy Programme.

More details can be found here: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=18723

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 27/03/2015; 15/NE/0106

Study design
Matched cluster randomised controlled trial with integrated process and economic evaluations

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Reproductive health and childbirth; Subtopic: Reproductive Health and Childbirth (all Subtopics); Disease: Reproductive Health & Childbirth

Interventions
REACH community: a community-based intervention that is designed and delivered in partnership with local community members which aims to support pregnant women to have their first antenatal appointment with maternity services before the 13th week of pregnancy, in line with national guidelines

Intervention Type
Other

Primary outcome(s)
The primary outcome measure, assessed at ward level, will be the proportion of pregnant women who have attended their antenatal booking appointment by the end of the 12th completed week of their pregnancy. Timepoint(s): All outcomes will be measured at baseline (T1), 2 – 7 months (T2) and 8-13 months (T3) post intervention start, using routine maternity service data.

Key secondary outcome(s))
1. Antenatal admissions
2. Emergency caesarean rates
3. Pre-term birth and low birth weight
All outcomes will be measured at baseline (T1), 2 – 7 months (T2) and 8-13 months (T3) post intervention start, using routine maternity service data.

Completion date
30/09/2023

Eligibility

Key inclusion criteria
Cluster RCT – inclusion criteria:
1. Trust level - Able to provide the routine maternity data required for randomisation and for assessment of outcomes. For both tasks we require 'gestation at booking' data and for outcomes assessment we also require data on various birth outcomes. All routine data is required at ward level.
2. Cluster (site) level - Electoral wards, covered by maternity care providers enrolled on the study, where the proportion of women who have their first antenatal appointment by 12 weeks is below the NHS national target of 90%. Electoral wards to be included in the study must also

be geographically spread out in order to reduce the potential for contamination in control sites.
3. Individual level - All women who are pregnant/give birth during the time frame of the study and live in one of the 20 intervention or control wards selected for the study. (There will be no active recruitment of participants as outcomes will be measured at ward level using routinely collected data).

Co-design process – inclusion criteria:
1. Any person (e.g. resident of local community, healthcare professional working in the community, community organisation volunteer or staff member) who is over the age of 16 and is interested in collaboratively developing intervention messages and materials for the local community concerning antenatal care.
2. Those co-design participants who match the inclusion criteria for peer volunteers (local women who share the same socio-demographic profile as groups vulnerable to late initiation of ANC) can continue their involvement through into the implementation and delivery phase.

Research interviews with co-design participants and peer volunteers – inclusion criteria:
1. We will potentially interview any person (e.g. resident of local community, healthcare professional working in the community, community organisation staff member) who participated in a community event, workshop, or other activity to collaboratively design content, messages and materials for the community intervention around antenatal care.
2. We will also interview peer volunteers who were involved in the co-design process and who delivered intervention messages and materials to local women within their communities.
3. We will only interview people over the age of 16.

Survey with pregnant women – inclusion criteria:
1. Pregnant women who live in intervention or control wards, and attend the antenatal clinic of a Trust enrolled on the study at least three months following the implementation of the intervention.
2. We will survey any potential participants aged 16 years and over who consent to the research. Any young women aged 16-18 years who we survey will have already been assessed by maternity staff as competent to provide informed consent to participate in antenatal care and maternity services (parental consent will not be requested for them to access services). As such, we believe that any young pregnant woman aged 16-18 years who is asked to take part in this survey will be competent to provide consent for themselves, without asking for additional consent from parents or guardians. Their inclusion in the research is vital, as this group is one at risk of higher rates of late access to ANC.

Target Gender: Male & Female; Upper Age Limit 100 years ; Lower Age Limit 16 years

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
Female

Total final enrolment
12068

Key exclusion criteria
Cluster RCT - exclusion criteria:
1. Cluster (site) level - electoral wards, covered by maternity care providers enrolled on the study, where the proportion of women who have their first antenatal appointment by 12 weeks is above the NHS national target of 90%. We will also not include electoral wards which are geographically close to one another, as this increases the possibility of contamination between intervention and control sites.
2. Individual level – women who are pregnant/give birth during the time frame of the study with the maternity care providers enrolled on the study, but who do not live in one of the 20 wards selected for the study.

Co-design process - exclusion criteria:
Anyone under the age of 16.

Research interviews with co-design participants and peer volunteers - exclusion criteria:
1. People within the intervention communities who are not involved in any aspect of the co-design process and/or the delivery of the intervention messages.
2. We will also not interview people under the age of 16 years.

Survey with pregnant women - exclusion criteria:
1. Pregnant women attending the antenatal clinic of a Trust enrolled on the study who do not live in intervention or control wards.
2. We will not survey anyone who is under the age of 16. Additionally, where maternity staff are concerned that a woman is not competent to consent to participate in services, then they will not be invited to participate in the survey research.

Date of first enrolment
01/04/2015

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

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Sponsor information

Organisation
City, University of London

ROR
https://ror.org/04489at23

Funder(s)

Funder type
Government

Funder Name
NIHR Programme Grants for Applied Research (UK); Grant Codes: RP-PG-1211-20015

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 05/01/2023:

Data that is suitable for open sharing will be stored (along with relevant metadata and documentation) in the City, University of London data repository, https://city.figshare.com/, without any restrictions (Open Data). As this data is anonymised/not personal no security will be required. This data will be reviewed every 5 years in accordance with City, University of London's Research Data Management policy (https://staffhub.city.ac.uk/_media/intranet-site/documents/policies2/research-and-enterprise/Policy-and-docs_revision-June-2022.pdf), and if appropriate destroyed.

Data that is not suitable for sharing will be securely stored in City, University of London Sharepoint data archive. Data is encrypted and only project personnel will have access to it. This security will be handled by City, University of London IT by restricting folder access.

A metadata-only record will be added to https://city.figshare.com/, to allow a record to be kept of data that has been created at City, University of London. There will be the same 5-year review, which will look at whether the data should be retained. In both cases, the destruction would involve the secure erasing of the data in consultation with City, University of London IT. The appraisal of the data after 5 years will be undertaken by the CI on the study (Angela Harden).

Previous IPD sharing statement:

Data that is suitable for open sharing will be stored (along with relevant metadata and documentation) in the UEL data repository, data.uel, without any restrictions (Open Data). As this data is anonymised/ not personal no security will be required. This data will be reviewed every 5 years in accordance with UEL Research Data Management policy (http://www.uel.ac.uk /wwwmedia/services/library/lls/resources/rspresearchtools/Research-Data-Management-policy-for-UEL-FINAL.pdf), and if appropriate destroyed.

Data that is not suitable for sharing will be securely stored in UEL's Arkivum data archive. Data is encrypted and only project personnel and UEL Admin staff will have access to it. This security will be handled by UEL IT by restricting folder access.

A metadata-only record will be added to data.uel, to allow a record to be kept of data that has been created at UEL. There will be the same 5-year review, which will look at whether the data should be retained. In both cases, the destruction would involve the secure erasing of the data in consultation with UEL IT. The appraisal of the data after 5 years will be undertaken by the CI on the study (Angela Harden).

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/12/2025	30/12/2025	Yes	No
Protocol article		05/03/2018		Yes	No
HRA research summary			28/06/2023	No	No
Preprint results		15/11/2024	10/02/2025	No	No
Statistical Analysis Plan	version 1.0	14/02/2023	20/02/2023	No	No