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Building Blocks - a trial of home visits for first time mothers

Submission date	Recruitment status	[X] Prospectively registered
24/03/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/04/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/09/2022	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.cardiff.ac.uk/medic/subsites/buildingblocks/index.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1.4

Study information

Scientific Title
Evaluating the family nurse partnership programme in England: a randomised controlled trial

Acronym
Building Blocks

Study objectives
The purpose of this study is to see if providing young first time mothers with extra support before and after the birth is helpful for both mother and child. We are specifically interested in whether the programme makes a difference to the mother and baby's health and behaviour:
1. During pregnancy and at birth
2. In the first two years after birth

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee (REC) for Wales, 17/02/2009, ref: 09/MRE09/08

Study design
Individually randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
First-time pregnancy

Interventions
This trial will assess the effectiveness of the FNP in England compared with existing universal services, in achieving its stated objectives (namely, to improve pregnancy outcomes, child health and development and parents' economic self-sufficiency).

The trial will start after consent and recruitment into the trial. Participants will be recruited into the trial as soon as the pregnancy is confirmed but before 24 weeks gestation. Participants will be randomised to either entry into the FNP programme arm or to the control arm (universal services), and will be followed up until 2 years after the birth of the child. The whole trial will last 52 months. Interviews (either face-to-face or by telephone) for both arms of the trial will be at baseline, 34 - 36 weeks gestation and 6, 12, 18 and 24 months after birth.

If participants are selected to join the group that receives the FNP programme, they will receive visits from a specially trained 'Family Nurse'. The Family Nurse would normally go to the participants' home, but can see you somewhere else if they prefer. The Family Nurse will visit the participant every week for the first month after they join the study, and then every other week until the baby is born. The Family Nurse will then visit the participant weekly until the baby is six weeks old and then once every two weeks until the child is 20 months old. The last four visits are monthly until the child is 2 years old.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Changes in prenatal tobacco use (maternal measure), measured at baseline and 34 - 36 weeks gestation interviews
2. Birth weight (child measure), measured at birth (collected afterwards)
3. Emergency attendances/admissions within two years of birth, measured at all timepoints
4. Proportion of women with a second pregnancy within two years of first birth, measured at all timepoints

Secondary outcome measures
1. Intention to breastfeed
2. Prenatal attachment
3. Injuries and ingestions
4. Breastfeeding (initiation and duration)
5. Language development
6. Education
7. Employment
8. Income/benefits
9. Home (tenure)
10. Health status
11. Self-efficacy
12. Social support
13. Paternal involvement

Timepoints not finalised as of 24/03/2009.

Overall study start date
06/04/2009

Completion date
19/09/2014

Eligibility

Key inclusion criteria
1. Women aged 19 years or under (at recruitment/consent)
2. Lives within the catchment area covered by the local family nurse partnership (FNP) team
3. First pregnancy confirmed by health services (including those expecting multiple birth) unless previous pregnancy ended in miscarriage, stillbirth or termination
4. Recruited no later than 24 weeks
5. Gillick competent to provide adequate informed consent to research participation including competence in English at conversational level or higher

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1600

Total final enrolment
1645

Key exclusion criteria
1. Women who at study entry, plan to have their child adopted
2. Women who at study entry, plan to leave the FNP area during the time of the trial either for an extended period of time (3 months or longer) or permanently
3. Women who would require a third person (translator, sign interpreter) to receive the FNP programme

Date of first enrolment
25/06/2009

Date of final enrolment
28/07/2010

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre

South East Wales Trials Unit (SEWTU)
Institute of Primary Care and Public Health
Cardiff University
7th Floor Neuadd Meirionnydd
Heath Park
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Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Policy Research Programme
Research and Development Directorate
NIHR CCF PO Box 407
Teddington, Middlesex
Teddington
United Kingdom
TW11 0XX

Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK) (ref: 006/0060) - Policy Research Programme

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/08/2013		Yes	No
Results article	results	09/01/2016		Yes	No
Results article	results	20/09/2016		Yes	No
Results article	results	05/05/2018	14/05/2019	Yes	No
Other publications	analysis	30/12/2019	02/01/2020	Yes	No
Other publications	economic evaluation	13/09/2019	04/06/2020	Yes	No
Results article		23/09/2022	29/09/2022	Yes	No