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Right from the start: Improving outcomes for children born to mothers in difficult circumstances

Submission date
28/02/2017

Recruitment status
No longer recruiting

Registration date
28/02/2017

Overall study status
Completed

Last Edited
05/02/2018

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Pregnancy is an important time for both mothers and their babies. For most people, it is a very positive time, when mothers-to-be can look forward to the arrival of a new child. But for some mothers, expecting a baby can be a difficult time. Some pregnant women have a lot of social problems to deal with, such as poor housing, domestic violence, or mental health problems. These problems can cause a lot of stress, which is not good for the baby or the mother. Problems like these can also get in the way of mother and baby developing a posiive relationship, and in some cases they can result in poor parenting. In the UK, midwives and health visitors provide care for all women during pregnancy and after the baby is born. For most mothers and fathers, this is enough professional support. For mothers with additional difficulties, more intensive support is sometimes needed. In recent years, the NHS has commissioned Nurse Family Partnership (NFP) as an evidence-based programme for young, socially disadvantaged first time mothers. No evidence-based programme is available for older first time mothers, or mothers who have already had one or more children, and so far the results from NFP in England have been disappointing. The New Baby Programme (NBP) was developed in Northern Ireland and provides a more intensive health visiting service than routine care. NBP Health Visitors make contact with mothers during their pregnancy and provide post-natal care for up to two years after the baby is born. The content of the programme is designed to reduce maternal stress, to help children and parents form good, secure relationships, and to help parents provide good care. The aim of this study is to test the NBP to find out what women think of the programme, if it is more helpful than routine care and if it would be possible to conduct a larger study.

Who can participate?
First time pregnant mothers over 19 years of age, or pregnant women who already have a baby, who are up to 20 weeks pregnant and in difficult life circumstances.

What does the study involve?
Women who agree to take part in the study are asked to sign a consent form and provide the researcher with some information about themselves. After that, women are randomly assigned

to one of two groups. Those in the fist group receive routine care during their pregnancy and after they have their baby. Those in the second group receive the New Baby Programme. This involves 30 home visits over the course of two years from a trained health visitor from when women are 20 weeks pregnant until the child is two years old. A member of the research team visits mothers in the both groups three more times. Once, when the baby is two months old, once when he or she is 6 months old, and finally when he or she is 12 months old. Each research visit takes approximately 45 minutes, and involves the researcher talking to mothers about their parenting experiences and about the support they have received. During the last visit, the researchers ask mothers if they can make a short video of them playing with their baby. Mothers do not have to agree to this if they don't want to.

What are the possible benefits and risks of participating?
Participants receive a service which they may find beneficial, however it is not known whether the study programme will be more beneficial than the standard programme. There are no notable risks involved with participating.

Where is the study run from?
1. Ulster Hospital (UK)
2. Ards Community Hospital (UK)
3. Bangor Community Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2015 to June 2018

Who is funding the study?
Research and Development Division of the Public Health Agency, Northern Ireland (UK)

Who is the main contact?
Professor Geraldine Macdonald
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 5 28-02-17

Study information

Scientific Title
Right from the start: Protocol for a pilot study for a randomised trial of the New Baby Programme for improving outcomes for children born to socially vulnerable mothers

Acronym
Right from the Start

Study objectives
Amongst mothers experiencing social complexity, babies born to mothers who receive support from home visitors trained to provide the New Baby Programme (NBP) will be more securely attached to their mothers than those whose mothers receive routine ante-natal and post-natal care, and will also experience a higher quality of maternal-child relationship. It is hypothesised that the NBP will improve maternal mental health and outcomes for children, at birth and during the first year of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Office for Research Ethics Committees Northern Ireland, 23/11/2015, ref: 15/NI.0232

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

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
Child development, maternal health and maternal-child relationships

Interventions
Participants are randomised to one of two groups using a central computer randomisation service (TENALEA).

Intervention group: Participants receive a manualised home visiting programme providing enhanced ante-natal and post-natal care designed to address the needs of mothers experiencing social complexities during and after pregnancy. The programme involves 30 visits over two years from a health visitor trained in the New Baby Programme. The visits will start at around 20 weeks gestation and will take place every month for four months until the baby is born. After that the health visitor will visit every week until the child is two
months old, then every two weeks until the child is four months old, and then once a month until the child is twelve months old, and finally every three months until the child is two years old.

Control group: Participants receive the Universal Core Programme recommended in the Healthy Child Programme through midwifery and health visiting services, and which is the routine package of care that will be offered to those who do not wish to take part in the randomised trial.

Follow up takes place when infant is aged 2, 6 and 12 months old.

Intervention Type
Other

Primary outcome measure
Parent-child relationship is assessed by measuring maternal sensitivity using the CARE-Index and child attachment using the Ainsworth Strange Situation Procedure (SSP) at baseline and 12 months.

Secondary outcome measures
Mother:
1. Parental mental health is measured using the Revised Prenatal Distress Questionnaire (NuPDQ) at 20 weeks gestation (baseline), the Edinburgh Post Natal Depression Scale (EPD) and the State-Trait-Anxiety Inventory (STAI-S-6) at baseline and when infant is aged 2, 6 and 12 months old, and the Parenting Stress Index at baseline and when infant is 2 and 12 months old
2. Smoking and substance use are measured using a series of brief questions at baseline, and when infant is 2, 6 and 12 months of age
3. Maternal quality of life is measured using the EuroQol (EQ-5D-DL) at baseline, and when infant is 2-, 6- and 12 months of age
4. Mother's sense of competence is measured using the Perceived Parenting Competence Scale (PSOC) when infant is 2 months and 12 months
5. Relationships violence is measured using brief questions at baseline and when infant is 12 months old
6. Social support networks are measured using the Medical Outcomes Study (MOS) Social Support Survey - short form 36, at baseline and when the infant is 12 months old

Child:
1. Child development is measured using the Mullen Scales of Early Learning when the infant is 2, 6 and 12 months of age
2. Service use will be measured by collecting information when the infant is 2, 6 and 12 months of age

Overall study start date
10/11/2015

Completion date
30/06/2018

Eligibility

Key inclusion criteria
1. First time pregnant mothers aged over 19 years, or multiparous women of any age presenting with socially complex circumstances, defined as one or more of the following
1.1. Social isolation/low family support/father in prison
1.2. Intimate partner violence
1.3. Substance misuse
1.4. Maternal stress or history of mental ill health
1.5. Current involvement with social services or probation
1.6. History of care or a care leaver
1.7. Abnormal reaction to pregnancy.
2. Capacity to provide informed consent

Participant type(s)
Patient

Age group
Adult

Sex

Female

Target number of participants
50

Key exclusion criteria
1. First time mothers under 19 years
2. Mothers experiencing no socially complex circumstances

Date of first enrolment
01/04/2016

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Ulster Hospital
Upper Newtownards Road,
Dundonald
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BT16 1RH

Study participating centre
Ards Community Hospital
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United Kingdom
BT23 4AS

Study participating centre
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BT20 4TA

Sponsor information

Organisation
Queen's University, Belfast

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Sponsor type
University/education

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Government

Funder Name
Research and Development Division, Public Health Agency, Northern Ireland

Results and Publications

Publication and dissemination plan
The results of the study will be submitted for publication in the journal Trials. If the results indicate it is appropriate, they will be used as the basis for a proposal for a full trial of the effectiveness of the New Baby Programme.

Intention to publish date
30/06/2019

Individual participant data (IPD) sharing plan
The current 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?
Protocol article	protocol	01/12/2018		Yes	No