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Evaluation of Lay Support In Pregnant women with Social risk

Submission date
27/07/2011

Recruitment status
No longer recruiting

Registration date
07/09/2011

Overall study status
Completed

Last Edited
07/03/2016

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Women who have problematic or challenging home situations or lifestyles are more at risk of developing problems with either themselves or their baby during pregnancy and after birth. This study is trying to find out if offering extra support to women having their first babies, in addition to that given by their midwife, has an effect on uptake of maternity care and the health and well being of mothers and their babies in the first 6 weeks after birth. The extra support is given by pregnancy outreach workers. They are lay workers who have been specially trained and work closely with the midwives. They give emotional and practical support during pregnancy and for 6 weeks after birth, as well as having good knowledge of the local community services available.

Who can participate?
Women having their first babies who are found to have problematic or challenging home situations or lifestyles are approached before 28 weeks of pregnancy and give consent to join the study.

What does the study involve?
All women are supported by their midwife as normal, but half will have extra support from a pregnancy outreach worker. Which group a woman is allocated is decided by chance (randomly) by a computer. The results from both groups will be compared to see if having this extra support from the pregnancy outreach worker improves attendance at antenatal appointments and the health of both mother and baby. The women will be asked to fill in a questionnaire to find out how the mother is getting on and how she is feeling 8 weeks after birth. Information about the pregnancy and birth will be collected from existing hospital information systems and routine information about the babys health check 6-8 weeks after birth and immunisations will also be collected.

What are the possible benefits and risks of participating?
There are no extra tests or visits for either mother or baby and no additional risk in taking part in the study. The trial is to find out if there is or is not any benefit to receiving the service.

Where is the study run from?
University of Birmingham. 3 Maternity Units: Birmingham Women's Hospital, Heartlands Hospital, and City Hospital. Lead Centre: Birmingham Women's Hospital

When is the study starting and how long is it expected to run for?
July 2010 to October 2011

Who is funding the study?
The study is being funded by the Birmingham and Black Country Collaboration for Leadership in Applied Health Research and Care (BBC CLAHRC)

Who is the main contact?
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Study website
http://www.bham.ac.uk/elsips

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RG 10_017

Study information

Scientific Title
Does the addition of lay support to current midwifery care for women with identified social risk factors improve health and psychological outcomes? A multicentre randomised controlled trial

Acronym
ELSIPS

Study objectives
Does the addition of lay support to current midwifery care for women with identified social risk factors improve health and psychological outcomes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Birmingham Research Ethics Committee, 16/03/2010, REC Ref: 10/H1207/23
REC Approved Amendments:
AM01: 14/04/2010
AM02: 25/05/2010
AM03: 16/11/2010
AM04: 14/04/2011

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Patient information can be found at http://www.birmingham.ac.uk/research/activity/mds/projects/HaPS/PHEB/ELSIPS/leaflets/PIL.aspx

Health condition(s) or problem(s) studied
Social risk in pregnancy

Interventions
The POW service is in addition to standard maternity care and will not be available to nulliparous women other than within the trial. Women assessed as having social risk and randomised to the intervention group will be referred to a POW who will provide individual case management including home visiting.

The purpose of the POW service is to ensure that women attend antenatal appointments and engage with required care, such as taking prescribed medication, attending scan appointments, and including making lifestyle changes, such as smoking cessation. The POWs also provide social support on such issues as ensuring that available benefits are obtained, housing difficulties are

dealt with, mental health problems managed and overall well-being is maximised. The philosophy underlying POW support is an attempt to help women to become more able to manage problems that arise in life, i.e. to enhance their general self-efficacy.

The POWs receive appropriate training to NVQ level 3 which is provided by Gateway Family Services and have access to supervision from experts with specific skills and knowledge. Postpartum POW contact will continue until 6 weeks after birth when transfer to the Family Support Worker (FSW) would take place for those who require it.

The control group receive support from midwives who currently either signpost women with social risk factors to services that may be beneficial or refer them to specialised agencies or personnel. This may mean they signpost to support agencies (for example, housing or benefit offices) or refer to other agencies (for example, social services), or refer onto the specialist midwives in their Trust. These specialist midwives act as a contact point and provide specific advice and support for women experiencing problems such as domestic abuse, mental health issues or who are teenagers when they are pregnant.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The primary outcomes have been chosen on the basis that they are linked to maternal and infant health.
1.1. Engagement with antenatal care, assessed based on number of antenatal visits and
1.2. Maternal depression, assessed using the Edinburgh Postnatal Depression Scale (EPDS) at 8-12 weeks after birth

Secondary outcome measures
Maternal outcomes will include:
1. Length of labour (first, second and third stages)
2. Mode of birth (spontaneous vaginal birth, instrumental birth or caesarean section)
3. Perineal trauma (episiotomy, degree of laceration)
4. Incidence of possible maternal morbidity (e.g., postpartum haemorrhage, shoulder dystocia, chorionamnioitis)
5. Length of stay in hospital
6. Engagement with other services, as required (e.g., smoking cessation service)

Baby outcomes are mainly markers of poor perinatal outcome
1. Composite outcome of adverse perinatal outcome comprising:
1.1. Perinatal mortality
1.2. Preterm birth before 34 weeks
1.3. Birth weight 10th centile or below
1.4. Admission to neonatal unit
2. Apgar score at 5 minutes
2.1. Arterial cord blood gases, if taken
2.2. Breastfeeding initiation rate
2.3. Length of stay in hospital
2.4. Oxygen at 36 weeks post conceptual age, if applicable

2.5. Retinopathy of prematurity, if applicable
2.6. Abnormal cerebral ultrasound prior to discharge (e.g., intraparenchymal cerebral bleed, hydrocephalus, parenchymal cysts), if applicable
2.7. Necrotising enterocolitis (Bells Stage I, II or III), if applicable
2.8. Culture positive sepsis requiring greater than 5 days antibiotic treatment, if applicable

Longer term infant outcomes
Routine child health assessments, including immunisation uptake and breastfeeding continuation at 6 weeks

Psychological outcomes
1. Self efficacy (using Pearlin and Schooler Mastery Scale)
2. Mother-to-infant bonding tool

Overall study start date
26/07/2010

Completion date
31/10/2011

Eligibility

Key inclusion criteria
1. Nulliparous women < 28 weeks gestation
2. Assessed by the midwife as having specified social risk through systematic assessment.

Nulliparous is defined as never having given birth to a child; this will include women who have had a miscarriage/s or termination/s of pregnancy. We have chosen under 28 weeks gestation as an inclusion criterion to give adequate time for the Pregnancy Outreach Worker (POW) service to impact on the outcomes.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1316

Key exclusion criteria
1. Those under 16 years of age due to the complexity of gaining informed consent from this group
2. Teenagers recruited to Family Nurse Partnership (FNP), but do not expect this to greatly affect recruitment to ELSIPS. One of the primary care trusts (PCTs) (South) participating in this trial is also involved in a national trial of additional support to pregnant teenagers, called the Family Nurse Partnership (FNP). The FNP intervention is health professionals providing intensive support throughout pregnancy up to 2 years after birth.

Date of first enrolment
26/07/2010

Date of final enrolment
31/10/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
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Sponsor information

Organisation
University of Birmingham (UK)

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Sponsor type
University/education

Website
http://www.birmingham.ac.uk

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Collaboration for Leadership in Applied Health Research and Care (CLAHRC)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	29/02/2012		Yes	No
Results article	results	02/03/2016		Yes	No