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Better care pathways in pregnancies after stillbirth

Submission date
12/02/2018

Recruitment status
No longer recruiting

Registration date
13/02/2018

Overall study status
Completed

Last Edited
17/08/2022

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
In the UK, 13 babies die shortly before or soon after birth every day, causing long lasting grief for parents. Most women who have had a stillbirth or neonatal death conceive again, often soon after the loss. Subsequent pregnancies are associated with high stress and anxiety for parents, increasing complications such as the baby being born too early or too small. Difficult feelings and emotions often persist, even after the birth of a healthy baby and can disrupt early bonding, making family and social problems more likely later in life. Sensitive and appropriate support is vital for parents in pregnancy after the death of a baby. However, our recent research demonstrated that not all parents had good care all of the time; tactless and insensitive communication and lack of emotional support were
common issues. This study examines whether it is possible to conduct research testing a new package of care to improve support for parents who have previously experienced death of a baby. Women would have a named midwife care-coordinator, who would deliver antenatal care alongside their doctor, maintain a relationship with the family in pregnancy and during the early days after birth and provide access to extra support. This change will be introduced with a small group of women in two hospitals in North-West England and compared with similar women who received care immediately prior to the change. This study assesses whether parents are willing to take part and stay in the research study, whether the change works as planned and the best ways of assessing the effect on well-being and maternity services. If this is study is successful then a larger study will be undertaken to assess whether this change would benefit women, represents good value for money and should be introduced to the NHS.

Who can participate?
Women aged 16 and older who are less than 20 weeks gestation and have experienced a stillbirth or a neonatal death of a previous baby and their partners. Health workers involved directly or indirectly involved in those providing care to women can also participate.

What does the study involve?
This study includes different phases. The first one to three to months include the study set up. The next three to eight months participants are recruited. During this time, they receive the existing care provided for women after previous death of a baby. Months nine to twenty consists of the second phase of recruitment where the new care package is introduced. The women

recruited during this phase receive a midwife care coordinator and a buddy widwife that provides support. Participants are able to contact their buddy and have access to a WhatsApp group. During the study, all participants are followed up at 30-37 weeks of pregnancy and 4-6 weeks after birth. Participants are asked about their anxiety, depression, health status and maternal-infant bonding. Women are also provided with a diary for them to record their thoughts and feelings. There are also interviews with participants, their partners and health care workers.

What are the possible benefits and risks of participating?
There are no direct benefits intended for participants during phase 1 of this study. During phase 2 it is hoped that the additional support delivered for the intervention will address deficiencies in care identified for women and families in previous exploratory work but this is cannot be guaranteed. Perinatal loss is an extremely sensitive area of maternity care with potential for women, partners and families affected by the death of baby and participating in research to suffer emotional distress. However, evidence suggests that women and families who have experienced the death of a baby around the time of birth find participation in research, particularly interviews helpful in allowing them to discuss events and their care in depth.

Where is the study run from?
1. Burnley General Hospital (Burnley)
2. Royal Oldham Hospital (Manchester)

When is the study starting and how long is it expected to run for?
January 2018 to December 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
36987

Study information

Scientific Title
Better maternity care pathways in pregnancies after stillbirth or neonatal death: A feasibility study

Study objectives
The aim of this study is to assess the feasibility of conducting a large-scale multicentre randomised controlled trial to test an intervention to improve psychological well being of parents who have previously experienced a
stillbirth (a baby born after 24 weeks of pregnancy, showing no signs of life) or neonatal death (a baby born alive, but died within first 28 days of life), through an improved maternity care pathway for the next pregnancy. Improving emotional and psychological support during subsequent pregnancies was ranked among the top ten research priorities identified by the recent James Lind Alliance Stillbirth Priority Setting Partnership. This multicomponent intervention, developed following our exploratory studies with parents and professionals, combines provision of a named midwife care coordinator and access to additional individual and group support activities during pregnancy after stillbirth or neonatal death. This package has been designed to improve continuity of care, foster emotional well being and enhance peer networks for parents during subsequent pregnancies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West Greater Manchester West Research Ethics Committee, 17/01/2018, ref: 18/NW/0010

Study design
Non-randomised; Both; Design type: Process of Care, Complex Intervention, Management of Care, Cohort study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Maternity care during pregnancy after stillbirth or neonatal death

Interventions
This prospective, observational mixed-methods study determines the feasibility of conducting a large trial of a new care package to improve the emotional and psychological support for parents in pregnancies after stillbirth or neonatal death. A pre- and post-observational cohort study over 36 months is conducted to allow assessment of important elements of the processes involved in a definitive trial within the limits of a feasibility study.

A total sample of 60 women (20 in the control phase (phase 1) and 40 in the intervention phase (phase 2) are recruited.
Partners (estimated up to 40 in total) are also recruited to explore experiences of subsequent pregnancy and the intervention through questionnaires and interviews. Birth partners (not woman's spouse or domestic partner) are recruited to take part in interviews where they are the main source of support for the woman. Health professionals (midwives, obstetricians, service managers) involved in care of women in pregnancy after stillbirth or neonatal death and in the delivery of the intervention in the two sites will also be recruited for interview (up to 15).

The first 1-3 months include the study set up. Months 3-8 phase 1 recruitment includes the usual care.

Over a six month period 10 women and partners in each of the two study sites (up to 20 weeks gestation who have previously experienced a stillbirth/neonatal death) are identified and approached via the clinical care team and recruited by the research midwife.

No national care pathway exists for women over pregnancy after stillbirth or neonatal death, therefore understanding of 'usual care' is limited. Planned data collection during the control phase allows detailed documentation of usual care in the participating sites. Participants recruited during months 3-8 have existing care pathway provided for women after previous perinatal death. Antenatal care normally be consultant-led, with appointments in the hospital and community clinics. Additional monitoring and investigations are requested according to clinical need, following national guidance. The standard antenatal education programme are available. Intrapartum care are provided in the obstetric unit and postnatal care by the community midwifery team, until transfer to primary care, up to 28 days after birth.

Recruitment is completed by end of month 8.

Months 9-20 consists of the Phase 2 recruitment: Intervention introduced, new care package

Over a twelve month period, 20 women per site (up to 20 weeks gestation who have previously experienced a stillbirth/neonatal death) are identified, approached and recruited as above to receive a new care package.

This involves being allocated a midwife care co-ordinator, with experience in caring for bereaved families and training in the intervention to improve continuity of care. The care co-ordinator works with a 'buddy' midwife also trained to provide the intervention to support and cover annual leave sickness and absence. The care co-ordinator also gets to know the woman and family through providing midwifery care during pregnancy as often as possible. They help the woman to make a plan for her pregnancy and birth, work with her obstetrician and other professionals to communicate clearly about care. They are also contactable at specified times should the woman need additional support or information for non-urgent concerns. The care co-ordinator remains in contact after the birth and during the early postnatal period to provide support eg by phone, although she may not directly provide postnatal care. The care co-ordinator midwives are trained by the study health psychologist to provide self-help advice to support women in coping with difficult feelings through a 'Coping Strategies Toolbag'. Women in the intervention group are also offered access to a monthly support group facilitated by midwives from the research and clinical teams on each study site to promote peer support. Session content will be flexible according to women's needs but includes targeted antenatal education appropriate to this group. A study 'WhatsApp' group are also available for women, moderated by the research team.

Data collection: During the study all the women participants (phase 1 and 2) meets with the research midwife at recruitment, 30-37 weeks and 4 to 6 weeks after birth. During pregnancy the appointments takes no more than 1.5 hours, the postnatal appointment would not be expected to last more than two hours.

Recruitment and retention data: Data on numbers of women who fulfill the eligibility criteria, who are invited to participate, the number recruited and women who leave the study before completion are kept. With permission, reasons for non-recruitment will also be recorded for women/ partners who have given contact details.

Demographic and clinical data: At the appointments the research midwife study completes case report forms using medical records and self-report to collect women's information including demographics, medical and social history, previous and current pregnancy data including all healthcare use and maternal and infant outcomes after the birth.

Psychological assessments: Women and partners (if participating) are also asked to complete a questionnaire containing several validated tools to assess a range of relevant psychological constructs including anxiety, depression, worry, health status and in the postnatal period, maternal-infant bonding and maternal self-efficacy.

Experiences of maternity care subsequent pregnancy, the care package and participation in the research.

Women are provided with a diary at recruitment. This has sections for recording thoughts and feelings about their pregnancy and care on a daily or weekly basis. Participants are informed that it is their choice whether to use these.
They are collected at the end of the study.

Views and experiences are explored through semi-structured qualitative interviews with a research assistant, in person, in a place chosen by the participant (e.g. home or private room in the hospital) or on the telephone if preferred.
Experience with previous studies indicates interviews with up to 12 women participating in phase 1, and up to 25 women participating in phase 2 are required to achieve data saturation, where no new ideas emerge. For partners up to 8 participating in phase 1, and 12 participating in

phase 2 are recruited. Interviews with women and partners
are scheduled for 4-6 weeks after the birth and if both partners agree they are interviewed separately. As not all women and partners will wish to participate or be available for an interview, all participants are approached at recruitment to ascertain their willingness. The study team will recruit up to 15 health professionals caring for women or
managing services during the study, they are approached directly by the research team towards the end of the data collection period in year 3.

Intervention Type
Behavioural

Primary outcome measure
1. Recruitment rates of women and partners recorded as the number of eligible participants who consent to take part, measured using the participant log, at the end of the study.
2. Retention of women and their partners recorded as the number of participants who remain in the study until completion, measured using the participant log, at the end of the study

Secondary outcome measures
1. Experiences of study participation and the intervention of parents and healthcare staff to determine the acceptability of trial processes and of the intervention. Explored through qualitative interviews, 4-6 weeks after birth (women and partners) and at the end of data collection (health professionals)
2. The characteristics of proposed psychological, cost-effectiveness, utility and clinical outcome measures will be examined in preparation for a definitive trial. These will be assessed by completion of validated self-report questionnaires (Generalised Anxiety Disorder 7 item scale (GAD-7) completed by women and partners at recruitment, 30-37 weeks and 4-6 weeks after the birth. Cambridge Worry Scale completed by women only at recruitment and 30-37 weeks gestation. Edinburgh Postnatal Depression Score completed by women only at recruitment, 30-37 weeks and 4-6 weeks after birth. Maternal-Infant Bonding scale completed by women only at 4-6 weeks after the birth. Maternal Self Efficacy Scale, (MSES) an 8-item scale to assess women's self-belief in their abilities to meet the needs of their infant, will be completed by women at 4-6 weeks after birth.Investigator designed case report forms (clinical outcomes)completed at recruitment, 30-37 weeks gestation and 4-6 weeks postnatal.
3. Elements of process evaluation will assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors impacting on outcomes. Fidelity will be assessed using the intervention logs completed by care co-ordinators during phase two, case report forms completed at 30-37 weeks gestation and 4-6 weeks after the birth and interviews with women and partners 4-6 weeks after birth and health professionals at the end of data collection

Overall study start date
15/01/2018

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Women and Partners:
1.1. Pregnant women over 16 years old and ≤20 weeks' gestation and have experienced a

stillbirth or a neonatal death of any previous baby
1.2. Partners, approached through the woman after she has agreed (a partner's unwillingness to participate will not affect the woman's continued participation)
1.3. Booked and planning have antenatal care at East Lancashire Hospitals NHS Trust or Pennine Acute Trust
1.4. For feasibility, sufficient command of English to participate in interviews and complete questionnaires will be required. Translation of materials will be explored with the aim of including parents lacking fluency in English in the definitive trial.
2. Health workers:
2.1. Midwives, obstetricians, service managers directly/indirectly involved in providing care to women participating in the study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 115; UK Sample Size: 115

Total final enrolment
78

Key exclusion criteria
1. Pregnant women/partners under 16 years
2. Women/partners who are already receiving care through a specialist antenatal service (eg diabetes, haematology clinics) as they would be receiving specialist midwifery/obstetric care relevant to their complex history.
3. Participants who are unable or unwilling to consent

Date of first enrolment
01/03/2018

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Burnley General Hospital
Casterton Avenue
Burnley
United Kingdom
BB10 2PQ

Study participating centre
Royal Oldham Hospital
Rochdale Road
Oldham
Manchester
United Kingdom
OL1 2JH

Sponsor information

Organisation
The University of Manchester

Sponsor details
Simon Building
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Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol and findings of the study will be published in high-impact clinical journals (e.g. BJOG, BMC Pregnancy and Childbirth and Midwifery) with open-access where possible around one year after the trial end date. The findings will also be presented at national multidisciplinary meetings including the Royal College of Midwives conference and the British Maternal Fetal Medicine Society and internationally at the International Stillbirth Alliance (ISA) meeting. The research team has established links with stakeholders and third sector organisations including Tommy's, SANDS and BLISS. Using our combined experience in writing for service users and the public we will produce material for the websites and social media. Feedback to participants and local stakeholders is of key importance; therefore we will organise a local dissemination workshop in month 35. Participants, families, clinical staff, operational mangers and stakeholders including charities and support groups will be invited to attend. A lay summary of findings will also be sent to all participants.

Intention to publish date
01/04/2022

Individual participant data (IPD) sharing plan
The 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?
Results article		10/08/2022	12/08/2022	Yes	No
Protocol file	version 2	05/02/2018	17/08/2022	No	No
HRA research summary			28/06/2023	No	No