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Antenatal care package to improve birth outcomes in subsequent pregnancies following stillbirth

Submission date
15/01/2020

Recruitment status
No longer recruiting

Registration date
17/01/2020

Overall study status
Completed

Last Edited
03/09/2021

Condition category
Pregnancy and Childbirth

[_] 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
Annually, there are at least 2.6 million stillbirths worldwide, 98% of which occur in low and middle- income countries of which a vast majority are preventable. The cause of stillbirth can often be complex as there are many contributing and interacting factors. One such factor is the increased risk of stillbirth in subsequent pregnancies after a previous pregnancy ended in stillbirth. However, there is no currently defined pathway for care in pregnancy following stillbirth in low and middle-income countries. Furthermore, little attention has been given to intervention studies in this population; in particular looking at ways women can be supported in a subsequent pregnancy to prevent future perinatal deaths.

This study will examine whether it is possible to conduct a large scale research study testing a specialised antenatal clinical service with psychosocial support and preparation for birth for women following stillbirth to improve birth outcomes. The specialised antenatal clinical service will be designed to improve the quality of antenatal care provision, reduce the risk of pregnancy complications, including stillbirth and give women a positive pregnancy experience. A psychosocial support and preparation for birth programme will be developed to enhance women' s pregnancy experience and help women approach birth positively.

Who can participate?
Pregnant women aged 18 years or above booking at the study site for antenatal care who have previously had a stillbirth, and female health workers who provide care of services to pregnant women at the study site.

What does the study involve?
Participants will be required to fill in questionnaires and take part in a focus group discussion as well as delivering/receiving care as usual.

What are the possible benefits and risks of participating?
Benefits: Women: may not benefit directly, however, it is hoped that the findings of the study will be used to advocate for the improvement of health services for women in a subsequent

pregnancy following stillbirth. The additional meetings with research assistants / midwives will give women the opportunity to talk about their previous stillbirth experiences. Healthcare workers: The participant may also feel empowered by their involvement in research that has the potential to influence further research that may improve maternity service provision.
Risks: Women: The following possibilities may occur during completion of questionnaires and focus group interviews: Discussion of topics or issues that might be sensitive, embarrassing or upsetting. Women and Healthcare workers: there is a potential for identifying poor practice during data collection.

Where is the study run from?
Mpilo Central Hospital, Bulawayo, Zimbabwe

When is the study starting and how long is it expected to run for?
September 2019 to January 2021

Who is funding the study?
National Institute for Health Research, UK. NIHR Global Health Research Units and Groups stream, The NIHR Global Health Research Group in Stillbirth Prevention and Management at The University of Manchester, UK.

Who is the main contact?
Prof Tina Lavender (scientific)
Tina.Lavender@lstmed.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Tina Lavender

Contact details
Liverpool School of Tropical Medicine
Pembroke Place
Liverpool
United Kingdom
L3 5QA
+44 (0)151 705 3100
Tina.Lavender@lstmed.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

43696

Study information

Scientific Title
Feasibility and acceptability of an antenatal care package to improve birth outcomes in subsequent pregnancies following stillbirth

Study objectives
To assess the feasibility of a full-scale evaluation trial to assess the effectiveness of specialised antenatal clinical service for women with subsequent pregnancies following stillbirth to improve birth outcomes for women in Zimbabwe.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 07/08/2019, Ethics Committee 4, University of Manchester (Research Governance, Ethics and Integrity, 2nd Floor Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, UK; +44 (0)161 275 2206/2674; research.ethics@manchester.ac.uk), ref: 2019-7237-11614
2. Approved 16/08/2019, Mpilo Central Hospital (Ministry of Health and Child Care, Mpilo Central Hospital, PO Box 2096, Vera Road, Mzilikazi, Bulawayo, Zimbabwe; +263 09-212011; no email provided), ref: none
3. Approved 22/11/2019 Medical Research Council Zimbabwe (Josiah Tongogara / Mazowe Street, PO Box CY573, Causeway, Harare, Zimbabwe; +263 (0)8644073772; mrcz@mrcz.org.zw), ref: MRCZ/A/2527

Study design
Mixed methods single-centre feasibility study using a pre and post-cohort design

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Pregnancy after stillbirth

Interventions
Phase 1: (Pre-implementation - control phase)

Women recruited during the control phase will have existing care provided for women with subsequent pregnancies following stillbirth. There is no current defined pathway for care in pregnancy following stillbirth. The control phase of the study will provide clearer understanding of usual care in the study site; refine content and delivery of the intervention and pilot data collection tools for the subsequent trial.
• A group comprising of women having the current standard of antenatal care at the study site will be recruited as controls to explore experiences of standard antenatal care, worries in

pregnancy and perceptions of preparation for childbirth by completing questionnaires at the beginning and towards the end of their pregnancy
• A sub-sample of women will also be invited to attend focus group interviews or individual interviews, whichever they prefer, at the end of their pregnancy to capture pregnancy experiences, including impacts of the intervention
• Health workers (midwives, nurses, obstetricians, and support staff), and other hospital staff, including managers and administrators, will be invited to attend focus group interviews to contribute to the refinement of the intervention and identify areas requiring a change of practice in the existing antenatal clinic area. The focus group interviews will identify the needs for education and training of staff and establishing care pathways for women attending the study site in a subsequent pregnancy following stillbirth
• Specialist antenatal clinical care staff will be identified to run the specialist clinic and provide psychosocial support and delivery of birth preparation information needs to the women in Phase 2 an obstetrician and two midwives and one support worker with an interest in this topic will be required
• Specialist antenatal clinical care staff will attend a training workshop (content based on existing educational resources, to be refined during Phase 1) to introduce the intervention, raise awareness of women's needs and identify areas requiring a change of practice in the existing antenatal clinic area
• Health workers (midwives, nurses, obstetricians, and support staff), and other hospital staff, including managers and administrators, directly involved in the intervention will be asked to complete a staff experience questionnaire at the end of Phase 1
• The proposed intervention has been informed by exploratory work from NIHR Global Health Research Group on Stillbirth Prevention and Management in Sub-Saharan Africa, and the Lugina Africa Midwives' Research Network (lamrn.org). The local Zimbabwe stillbirth Community Involvement and Engagement group, local women who have experienced a stillbirth, will be asked to contribute to the refinement and implementation of the proposed antenatal clinical service (July/August 2019)

Recruitment:
Individual consent will not be sought for attendance at either the current antenatal clinic (control phase 1) or the proposed specialised antenatal clinic (intervention phase 2), as both are considered standard practice. The current antenatal clinic running throughout Phase 1 will be superseded with the specialised antenatal clinic in Phase 2 of the study period. Both will be provided for all women attending antenatal services at the study site who have experienced a previous stillbirth, irrespective of their participation in the study/questionnaire completion /focus group/individual interview participation.

Consent will be sought for data collection associated with the assessment of the feasibility of a full-scale trial, acceptability and uptake of the intervention for women and facility staff. Identification of women with a history of stillbirth will be undertaken by appropriately trained and experienced members of the clinical team and confirmation of eligibility and consenting of participants undertaken by research assistants/midwives.

Women:
Eligible women will be initially identified and approached via a member of the clinical care team at the woman's hospital booking appointment who will introduce the study. If permission to consider the study has been granted, they will notify the research assistant/midwife to discuss the study further. Written and verbal information (available in local languages) will be supplied and potential participants will be given time to consider participation. The woman will be encouraged to discuss with family/others (if accompanying her) and provided additional opportunities to ask questions. She will be informed that her participation is voluntary and a

decision not to take part in the research will have no impact on her current or future healthcare provision. Women will be given the opportunity to confirm participation at the booking visit should they wish and provided with the consent form to sign. Others will be given the opportunity to confirm participation at their next antenatal clinic appointment, where consent form completion will take place. Women will be able to withdraw up until 1 week after taking part in the interviews.

Health workers (midwives, nurses, obstetricians, and support staff) and other hospital staff, including managers and administrators:
Staff and others directly involved in the delivery of the intervention will be informed about the research during workshops facilitated by the research team at the beginning of the study. They will be invited to contact the research team directly if they are interested in participating and given a written and verbal explanation. Potential participants will be reassured that they are under no obligation to participate and can withdraw at any time up to 1 week after the focus group interview. They will be asked for permission to re-contact by their preferred method, once they have had time to consider participation and not less than 24 hours later. If the health worker or other agrees to participate, they will be provided with the planned date of the focus group interview (Phase 1 & 2). On the agreed focus group date, the research assistant/midwife will bring the study information and consent form and will take approximately 10 minutes to discuss the study and read through the consent form with the potential participants in order to ensure that the content is well understood. A further opportunity will be provided for questions to be asked of the researchers. If the potential participant agrees to take part, they will be asked to sign the consent form.

In addition, at the end of phase 2, the health workers in the facility will be invited in writing to complete a short, anonymous paper questionnaire to assess awareness of the research, experiences of either routine antenatal care or the intervention and to capture any wider impacts on practice. The questionnaire will be accompanied by participant information, return will be taken as confirmation of consent.

Phase 2: (Specialised antenatal clinical care with psychosocial support and preparation for birth – intervention phase)

The proposed specialised antenatal clinical service will be designed to improve the quality of antenatal care provision, reduce the risk of pregnancy complications, including stillbirth and give women a positive pregnancy experience. The clinic will comprise two major components: specialised antenatal clinical care and psychosocial support and preparation for birth. Women will be considered high risk, have continuity of carer, an individualised structured care plan and regular antenatal appointments. The clinic will adhere to guidelines set out by WHO Recommendations on antenatal care for a positive pregnancy experience (WHO 2016). A psychosocial support and preparation for birth programme will be developed to enhance women' s pregnancy experience and help women approach birth positively. The programme will comprise specialist antenatal classes for women including preparation for birth, and recognising and managing worry. Women will be offered the opportunity to build relationships with other women to enhance social support during pregnancy. The precise content and delivery of the programme will be finalised during this phase.

The intervention will be implemented in the study site.
• The specialised antenatal clinic will be launched at the study site. The specialist antenatal clinical care staff will initiate this with support from a research team facilitator, research assistants/midwives, and hospital staff including managers and administrators
• Specialist antenatal care, including psychosocial support and a preparation for birth

programme will be delivered by the specialist antenatal clinical care staff, with support from the research team facilitator
• Women booking at the study site will be recruited during months 4 and 5 to explore experiences of attending the specialised antenatal clinic, worries in pregnancy and preparation for pregnancy and asked to complete questionnaires, at the beginning and towards the end of their pregnancy. A sub-sample of women will also be invited to attend focus group interviews or individual interviews, whichever they prefer, towards the end of their pregnancy to capture pregnancy experiences, including impacts of the intervention
• Monthly meetings (attended by the specialist antenatal clinical care staff, research team facilitator, hospital staff including managers and administrators) to share experiences and develop further strategies to improve clinical care practice and outcomes for women will be planned
• Health workers (midwives, nurses, obstetricians, and support staff), and other hospital staff, including managers and administrators, directly involved in the intervention will be asked to complete a staff experience questionnaire and offered the opportunity to attend a focus group interviews at the end of Phase 2

Intervention Type
Behavioural

Primary outcome(s)
1. The key feasibility outcomes will be recruitment and retention of women in the study.
Other outcomes will include:
2. Acceptability and uptake of the intervention and experiences of study processes which will be explored through questionnaires and interviews with women and healthcare staff (midwives, nurses, obstetricians, and support staff), involved with the delivery of antenatal care
3. Psychological measures:
3.1. The extent and content of worries in pregnancy (women) measured using the Cambridge Worry Scale at baseline (at first visit to antenatal clinic at the study site) and outcome (at the end of their pregnancy) (both Phase 1 and 2).
3.2. Knowledge, attitudes and perceptions of preparation for childbirth (women) Birth Preparedness and Complications Readiness Tool at baseline (at first visit to antenatal clinic at the study site) and outcome (at the end of their pregnancy) (both Phase 1 and 2).
3.3. Questionnaire to assess awareness of the research, experiences of either routine antenatal care or the intervention and to capture any wider impacts on practice (women & staff) at baseline (at first visit to antenatal clinic at the study site) and outcome (at the end of their pregnancy) (both Phase 1 and 2) for women and baseline (at time of recruitment to study) (phase 1 & 2) and outcome (at end of recruitment of women (for phase 1) and when last woman delivered (for phase 2)) for health care staff.
4. Clinical measures:
4.1. Investigator-designed case report forms will be used to collect data for women participants via patient health records (including hospital, patient-held and electronic records) and self-report (where no secondary source available): Demographic (age, ethnicity, socioeconomic status [highest level of education, occupation]) medical (history, body mass index, smoking status, medication use), obstetric history (previous pregnancies, mode of birth, outcomes), current pregnancy and outcome. Previous stillbirth data including the onset of labour, mode of birth, maternal and infant outcomes, cause of death (if known) length of hospital stay, and postnatal complications/all healthcare utilisation (for example; antenatal visits to the hospital, ultrasound scans) and access to external support will be collected. Data will be collected at recruitment and birth (study completion)
4.2. Basic demographic data (age, job title, year qualified, area of work) will also be collected via

self-report for participating health workers and support staff at recruitment (staff)
4.3. Human and healthcare resources associated with delivering the intervention

Key secondary outcome(s))
N/A

Completion date
31/01/2021

Eligibility

Key inclusion criteria
1. Pregnant women 18 years or over, at the time of recruitment, booking at the study site for antenatal care (during Phases 1 and 2) with subsequent pregnancy following stillbirth (baby born dead at 28 weeks gestation or more, with a birth weight of 1000grams or more or a body length of 35cm or more (WHO, 2019))
OR
2. Health workers (midwives, nurses, obstetricians, and support staff), and other hospital staff, including managers and administrators directly involved in the study intervention or who provide care of services to pregnant women at the study site

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
80

Key exclusion criteria
Unable to give consent (pregnant women group)

Date of first enrolment
02/09/2019

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
Zimbabwe

Study participating centre
Mpilo Central Hospital
Vera Rd
Mzilikazi
Bulawayo
Zimbabwe
P.O. Box 2096

Sponsor information

Organisation
University of Manchester

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

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Tina Lavender; Tina.Lavender@lstmed.ac.uk. Type of data: Anonymised quantitative and qualitative. Available following the full publication of findings and for 5 years following completion and publication of results.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet version v1.1	11/11/2025	11/11/2025	No	Yes
Protocol file		19/08/2019	05/02/2020	No	No