PROTOCOL

Advancing care and support for women and families after stillbirth or neonatal death in Uganda and Kenya: A feasibility study

Version 1.1_UG
24/07/2019

Contents

1. RESEARCH TEAM & KEY CONTACTS

Chief Investigator:

Name: Professor Dame Tina Lavender

Address: Division of Nursing, Midwifery and Social Work, School of Health Sciences, Faculty of Biology, Medicine and Health, The University of Manchester
Jean McFarlane Building
Oxford Rd
Manchester
M13 9PL

Email: tina.lavender@manchester.ac.uk
Telephone: 0161 306 7744

Co Investigators:

Dr Tracey Mills, Senior Lecturer in Midwifery, Division of Nursing, Midwifery and Social Work, The University of Manchester

Professor Karina Lovell, Professor of Mental Health, Division of Nursing, Midwifery and Social Work, The University of Manchester

Dr Carol Bedwell, Senior Lecturer in Global Women's Health, Division of Nursing, Midwifery and Social Work, The University of Manchester

Professor Alexander Heazell, Professor of Obstetrics, School Of Medical Sciences,The University of Manchester

Dr Chris Sutton, Senior Lecturer in Clinical Trial Statistics, Manchester Clinical Trials Unit, The University of Manchester

Dr Lucie Byrne-Davis, Senior Lecturer in Health Psychology**,** The University of Manchester

Dr Elizabeth Camacho, Senior Research Fellow in Health Economics, The University of Manchester

Prof Grace Omoni, Associate Professor, School of Nursing Sciences, University of Nairobi, Kenya

Ms Elizabeth Ayebare, Lecturer, College of Health, Makerere University, Uganda

Ms Claire Storey, Parent Advocate, International Stillbirth Association Board Member

Ms Valentina Actis Danna, Research Associate, Division of Nursing, Midwifery and Social Work, The University of Manchester

Sponsor(s):

Name: The University of Manchester
Address: Oxford Rd, Manchester M13 9PL, United Kingdom
Telephone: +44(0)1613066000

2. INTRODUCTION

Globally, 2.6 million babies a year die shortly before; during or soon after birth. More than half of these deaths occur in Sub-Saharan Africa, where the average rate is about eight times higher than in wealthy nations[2]. It is well established that stillbirth is a distressing and traumatic experience for parents with long lasting effects such as depression and other serious mental health issues, which are linked with higher rates of physical health problems, relationship and family breakdown[3]. Reducing the impact of stillbirth has been identified as an important international health priority for sustainable development[4]. Preventing as many stillbirths as possible through improvements in maternity and general healthcare is very important, but it is also imperative that good care is provided for women and families whose baby dies. Research across many different countries has shown that parents are not always treated with respect and compassion or offered the support they need after stillbirth[5]. This is important; all people wherever they live should have a right to expect basic humane care after death of a baby[6]. Poor experiences with healthcare can impair adjustment and recovery, impair parent's ability to care for others (including remaining children) and also might deter them from accessing health services when the need arises in the future[7]. A study in eastern Uganda showed that the health system and community support structures were inadequate in providing support to affected families [8]. Our recent research in Kenya and Uganda also identified lack of support for parents in facilities and after discharge home in Kenya and Uganda. Common practices surrounding stillbirth in some countries, including not being encouraged to see and hold stillborn babies and lack of public mourning caused distress to parents [9]. Lack of education and support from health systems made it more difficult for professionals to provide good support.

This study will examine the acceptability and feasibility testing of a new package of care to improve support for parents after stillbirth or neonatal death in Kenya and Uganda and the feasibility of a full-scale trial to evaluatethe effectiveness of the package. Health workers and support staff with an interest in bereavement care in two facilities will come together forming a Perinatal Bereavement Care group which will act collectively to develop strategies to improve care for women and families. Members will act as Bereavement Champions to drive improvement in individual clinical areas. A network of community peer supporters linked to the group will be developed to offer telephone support to women in the early postnatal period. This change will be introduced with a small group of women in two hospitals in Kenya and Uganda and compared with similar women who received care immediately prior to the change. We will assess 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, we will seek funding for a full scale trial to assess whether this change would benefit women, represents good value for money and should be introduced more widely in similar settings.

3. BACKGROUND

Of an estimated 2.6 million annual global stillbirths, 64% occur in Sub Saharan Africa. In 2015, stillbirth rates for Kenya and Uganda were 22.5 and 21 per 1000 births, respectively, around 10 times those reported in high resource settings[2]. The death of a baby, before or during birth is acknowledged as among the most traumatic and distressing life experiences with profound and long-lasting impacts for parents. Psychological distress is common and associated with significant short and long term adverse childbirth, mental health and social outcomes for bereaved families [3]. Justifiably, considerable current effort is being focused on developing strategies to improve the quality of maternity care and reduce preventable stillbirths worldwide[12]. However, the recent Lancet Ending Preventable Stillbirth Series[13]also emphasised the importance of ensuring humane and responsive care and support for women and families who experience the death of a baby. This call reflects evolving understanding of the significance of respectful maternity care which should 'encompass respect for women's basic human rights, including respect for women's autonomy, dignity, feelings, choices, and preferences, including choice of companionship wherever possible' [14].

Evidence from high-income, low-burden settings demonstrates that empathetic and compassionate care from health workers positively enhances parent's adjustment and recovery after stillbirth, their ability to care for others and future contacts with health services[7]. Open and supportive relationships can also benefit health workers in addressing their emotional responses to poor outcomes and enhancing professional resilience and job satisfaction. However, studies across international health systems, mainly focused on high resource settings, demonstrated considerable inequities. Lack of training, formal guidance, support and resources combine with the result that many women and families do not receive high-quality individualised bereavement and postnatal care [15]. In the wider context, evidence also suggests that the extent and duration of the emotional and psychological impacts of stillbirth for women and families is underestimated. Cultural norms and taboos including lack of acknowledgment of the baby, rapid burial with limited ritual and restrictions on public mourning, common across many cultures, including parts of Africa, are also potential contributors to disenfranchised grief [16].

Our recent qualitative work in urban and rural settings in Kenya and Uganda has increased understanding of the experiences of parents and health workers (NIHR Global Health Research Group on Stillbirth Prevention and Management in Sub-Saharan Africa at the University of Manchester). Overall, care provision was variable and rarely met parents' needs. Parents reported significant lack of information around the baby's death and care provision. Insensitive or inappropriate communication from health workers and support staff was also frequently reported. Opportunities for creating memories of the dead baby were infrequent. The environment of care also created anxieties for women, who were not routinely separated from others with live babies in the immediate postnatal period. Experiences were impacted by inflexible and unsupportive institutional policies surrounding identification and handling of the dead baby and access to

continuous support from family and friends. Parents perceived they had limited agency, choice and control over their care in facilities. Women and partners had minimal contact with health workers after discharge and relied on support from family, friends and the wider community which was not always available. Cultural taboos and superstitions surrounding stillbirth, frequently raised as an issue, prevented open acknowledgment of the death and compounded parents' sense of isolation and abandonment. Health workers found interactions with parents difficult and sometimes distressing. They reported feeling unprepared for this part of their role, with very few recalling any specific pre or post registration education to develop skills. Excessive workload and perceived emergence of a 'blame culture' surrounding poor outcomes also impacted on abilities to respond to parents' needs.

Importantly, these findings have some similarities with parents' and staff members' experiences in high-income settings where developments in care and support in the past three decades have made a significant difference to parents' experiences. However, evidence to support specific interventions to improve outcomes for families after stillbirth or neonatal death is sparse [17]. A 'one size fits all' approach would not be appropriate and interventions should take account of social, cultural and healthcare system diversity across settings. Broad expert consensus reinforced by accumulating data reflecting a spectrum of experiences, including our work in Kenya and Uganda, supports the need for respectful care, provision of information and creation of memories of the baby [18]. These activities are contingent on raising awareness and education of staff and strategies to promote improved practice. Improving care in facilities is likely to have a positive impact on wellbeing, but hospital stay is usually only a few days. For many women and families, the need for support and information might increase after the initial shock of the death has passed and once they are discharged from hospital, however follow up, particularly in low income countries (LICs) is often inadequate. Currently in Uganda, the guidelines recommend that families who have experienced a stillbirth be offered support by healthworkers, allowed to perform their local customs on the baby and be given a death certificate for the baby [19]. It is not known to what extent these guidelines are practiced and no follow up plan is suggested.

In high income countries (HIC), peer support networks developed to fill this gap in services. This concept, involving support from someone who has experienced a similar life situation or health problem [20], has been demonstrated to have positive benefits for women experiencing emotional distress, although robust evidence for impact after pregnancy loss is lacking [21]. Peer support encompasses a range of experiences from informal lay support, to highly trained supporters who may adopt and identify with a paraprofessional role. Support can be delivered in various ways including face to face groups, telephone contact or online [22], offering sustained contact that would not be possible using professional resources alone. Peer support is not designed to replace professional psychological or psychiatric therapy, however profound distress is part of normal grief after the death of a baby and only a minority of parents will require specialist care.

There is increasing acknowledgment of difficulties in translation of increased knowledge amongst health care workers into changes in practice. Appropriate leadership and support structures within

practice environments to drive innovation are now recognised as of key importance. Amongst potential strategies, utilisation of 'change champions' has been associated with successful implementation of interventions across different healthcare contexts [23]. There is no single definition of this role, but it is generally considered to denote individuals who are; 1. internal to an organisation, with 2. an intrinsic interest and commitment to promoting change, 3. are prepared to work diligently towards change (even with little formal recognition) and are 4. enthusiastic, dynamic, energetic, personable and persistent and have 5. strength of conviction[24]. Change champions work individually and collectively to embedding and sustaining service improvement in other areas of health care, but their role in supporting improved practice in maternity care in LMIC has not been extensively explored.

On-going co –production activities, following our NIHR Global Health Group exploratory work, involving established stakeholder (multidisciplinary health professional, academic and policy makers in-country) and community engagement groups (service users with experience of perinatal death) has recognised the potential of an intervention encompassing change champions to improve care in facilities and developing peer networks to provide ongoing support to women in the early postnatal period. The intervention will be focussed on two 2 major components, informed by exploratory data from NIHR group year 1 and 2, supported by stakeholder and community engagement group input in Kenya and Uganda. The precise content and delivery will be finalised during the ongoing co-production workshops a scheduled during July/August 2019, and will be adapted to suit the local context in each country. Component 1: a PerinatalBereavement Care Group formed of bereavement care champions and other stakeholders across each facility will address the development of capability, opportunity and motivation of staff in order for them to deliver optimal care in the new care pathways and establishing care pathways for women and families in facilities after death of a baby. Component 2: A peer support programme will be developed to enhance social support for women in the early postnatal periodafter discharge from facilities.

4. STUDY OBJECTIVES

4.1 Aim: To assess the feasibility of a full scale evaluation to assess the effectiveness of a co-produced multicomponent intervention to improve immediate care in facilities and postnatal support after stillbirth or early neonatal death for women and families in Kenya and Uganda.

4.2 Objectives:

1. Finalise a multicomponent intervention to improve immediate care in facilities and postnatal support after stillbirth or early neonatal death for women and families in Kenya and Uganda.
2. The objectives for feasibility are:
    2.1. To explore the acceptability, implementation and uptake of the key components of the intervention to women receiving the peer support intervention, peer support facilitators delivering the intervention and Perinatal Bereavement Care Group
    2.2. Explore impacts of the research on practice/services and delivery of the intervention.
    2.3. Assess recruitment and retention of women into the study

3. To prepare a for a full scale evaluation of the intervention package.
   Specific activities are to:
   3.1. Define the most appropriate primary and secondary outcomes to assess the effect of the intervention in a full-scale trial.
   3.2. Assess the acceptability and burden associated with data collection for participants.
   3.3. Use data to optimise the design and estimate the sample size required for a full-scale effectiveness trial.
   3.4. Determine the feasibility of an economic evaluation, through an exploration of key resources associated with implementing the intervention and how these may be reliably captured
   3.5. To utilise existing and develop additional networks to identify potential sites for a full-scale trial.
4. To synthesise all feasibility, acceptability and uptake data, to develop a full trial protocol at the end of the study.

5. STUDY DESIGN & PROTOCOL

5.1. Methodology: Following the MRC framework for developing and testing complex interventions in health care [25] this prospective mixed-methods study will be conducted, guided by a participatory approach. This study will follow action research; an empowering, transformational methodology which embraces participation and fosters co-production between stakeholders including researchers, practitioners and service users [26]. The focus is on co-operation to address issues identified in practice which can be evaluated, providing an evidence base to improve the quality of care [27]. Action research is based on cycles (Figure 1) of problem identification, planning change and action to implement change. The iterative nature of this approach is evident in the final phase where observation and reflection on the process and consequences of change frequently raises new questions and problems [28]. These can be addressed by initiating further cycles, allowing progression of the investigation to a more extensive understanding of the issue as a whole.

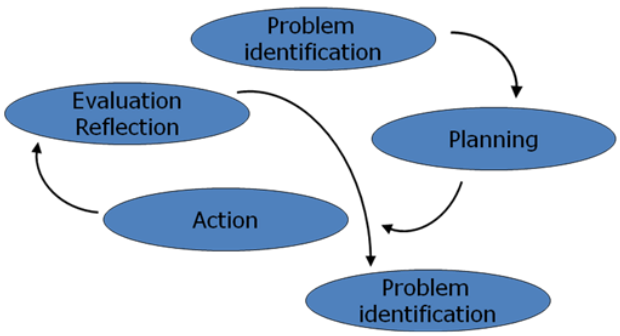


Figure 1: Action research spiral, adapted from Kemmis and Mc Taggart [1].

Action research has particular advantages for initiating, managing and implementing changes in clinical practice [27]. Stakeholder participation throughout the research process means that service providers and users are active participants in the research, as opposed to the traditional role of passive subjectivity. The emphasis on continuous evaluation and reflection means that the content and direction of the research evolves in response to findings and is kept under constant review. Implementation of any new approach requires health workers to change their practice. Therefore, the participatory approach will be complemented with use of the Behaviour Change Wheel [29], a structured approach to designing behaviour change interventions, which has been used in participatory implementation research in UK[30]. The planned intervention has been informed by a review of the literature and exploratory qualitative data generated during the current NIHR Global Health Group work streams in Kenya and Uganda. The proposed components will be refined by co-production activities involving established stakeholder and community engagement groups currently supporting the NIHR Global Heath Research Group on Stillbirth Prevention and Management in country, prior to the research commencing. Training materials will be adapted for the local context, based on a scoping review of existing resources and review by stakeholder and community engagement groups.

For a full-scale evaluation, individual randomisation may be undesirable due to the risk of contamination between the trial arms and the organisational-level changes required by the intervention. A stepped-wedge (one-way crossover) design in which intervention is rolled out in phases, the order determined at random but all clusters receiving the intervention by the end of the trial, could be considered as potentially appropriate. For feasibility, a pre and post cohort design, over 12 months, will be conducted to allow implementation of the intervention in two sites and assessment of the feasibility.

5.2. Setting: Tertiary maternity facilities in Kenya (Kenyatta National Hospital, Nairobi, Kenya) and Uganda (China-Uganda Friendship Hospital, Naguru, KampalaUganda). China-Uganda Friendship Hospital, Naguru (CUFHN) is located in Nakawa division in Kampala city. The hospital has recently attained regional referral status, it is a training hospital and has a bed capacity of 100 beds. It primarily serves people from Nakawa division in Kampala city but also recieves clients from Kira town council, Makindye division, Kawempe, Kitebi, Kisenyi and as far as Mukono district. The maternity unit has a monthly antenatal attendace of approximately 1900 women and 600 deliveries. The number of stillbirths and ealry neonatal deaths is approximately 15-20 monthly. Postnatal women are observed for around 6 to 72 hours after birth before discharge depending on the mode of delivery. The maternity unit has a total of 38 health workers (1 senior consultant, 1 specialist, 3 Medical officers, 3 Senior Nurisng Officers, 13 Nursing Officers and 17 Enrolled Midwives. The hospital also 2 social workers who offer psychological support to patients in need.

5.3. Kenyatta National referral Hospital is Kenya's largest hospital. It is a public tertiary hospital with a busy maternity unit having approximately 1200 deliveries and about 40 stillbirths per month. **Participants:**

During the recuitment periods we will approach as many eligible women meeting the inclusion critieria as possible. We will aim to recruit up to 40 to 60 women in each phase per country (total sample 80-120), who have experienced a stillbirth or neonatal death in the index pregnancy, to assess the feasibility of data collection, and in phase 2, to offer the peer support component, explore experiences of the intervention and study participation. In phase 1, up to 60 women (up to 30 per country) having the current pattern of care at the same units, in the period preceding the introduction of the intervention will be recruited. In phase 2 (intervention) up to 60 women (30 per country) will be recruited.

In phase 2, partners (or the support person as defined by the woman) of women participants (maximum sample of up to 30 per country, phase 2, total up to 60) and health workers and others (eg peer supporters) delivering the intervention (up to 15 per country) will be recruited to explore experiences of the intervention and participation in the research. Where women agree, partners or family members will be approached, although it is recognised that not all will want to participate

Health workers involved in providing/managing care for women after stillbirth or neonatal death in the included facilities will be recruited to complete a short questionnaire survey, at the end of the study, to assess experiences of the intervention and capture wider impacts of the research on practice.

5.4. Study phases:

5.4.1. Phase 1 (Pre-implementation; months 1-6)

5.4.1.1. **Phase 1 data collection (usual care**) In months 3 and 4, we will recruit up to 30 women per country, who have experienced a stillbirth or early neonatal death of their baby in the current pregnancy, having current standard care provided at participating facilities. Women will be asked to complete questionnaires 6-8 weeks after birth.

5.4.2. Phase 2 Intervention (months 7-12): The intervention will be implemented in both sites in month 7. In month 7-9 we will recruit a separate group of up to 30 women per country (as above). The women will be offered the peer support component after recruitment and asked to complete questionnaires and an interview to explore experiences of the intervention approximately 8-12 weeks after the birth.

5.4.2.1. Component 1: Perinatal Bereavement Care Group and Perinatal Bereavement Care Champions

- Perinatal Bereavement Champions will be identified in each area providing care for bereaved families (labour ward, postnatal ward, antenatal clinic, neonatal unit). Two

health workers/ support staff with an interest in this topic will be required in each area. This group will be comprised of 8-12 people.

- Perinatal Bereavement Champions will be invited to a training workshop (content based on exisiting educational resources, to be refined during co-production during Phase 1, and to include behaviour change techniques that address capability, opportunity and motivation) during months 5/6 to introduce the intervention, raise awareness of parents needs, behaviour change techniques to support other staff to change practice with other staff and identify areas to develop and barriers to changing practice in their area. This training will also address their role in supporting the peer volunteeers.

- Perinatal Bereavement Champions will hold a Perinatal Bereavement Care Group meeting monthly from month 7, with additional representation from a research team facilitiator, hospital management and community engagement representatives to share experiences and develop facility-wide vision and strategies to improve bereavement care practice and outcomes for parents.

5.4.2.2. Component 2: Postnatal peer support network

- A postnatal peer support programme will be initiated, hosted by each partipating maternity facility and supported by Perinatal Bereavement Care Group and identified Bereavement Champions

- Volunteer parent peer supporters (4-6 per facility) will be recruited via existing networks (community engagement groups, community health contacts, etc.)

  Criteria for peer supporters: women with personal experience of stillbirth or neonatal death, at least 12 months prior to participation in the programme and not currently experiencing severe mental health issue

  - Volunteers will be provided with training, a two day workshop covering perinatal death, grief processes and complicated grief, listening and communication skills, cultural and spiritual considerations, self-care, confidentiality and boundaries will be held during phase 1. This will be developed during co –production actvities in phase 1.

  - 'Terms of Use' for peer support, e.g. times of availibility, expectations, managing contacts will be agreed locally with peer supporters and the Perinatal Bereavement Care Group. Written information will be developed and provided to women on accessing the the service and for peer supporters.

  - Women experiencing a stillbirth or neonatal death and recruited to the study during months 7-9, will be provided information about peer support at recruitment, peer support programme contact details, women will be asked to

send message to a closed whats app group or SMS or make a phone call to initiate contact. This will be moderated by the local research team. They will be matched with a peer supporter in their local area.

- Support will be delivered only by telephone calls or/ SMS or messaging apps eg Whatsapp. Therefore peer supporters will be provided with study specific mobile phones to be used solely for this purpose. They will be instructed not to divulge personal contact details or addresses to women in any circumstances.

- Peer supporters will be linked with a named health worker (member of the Perinatal Bereavement Care Group) in the facility for debriefing, support with any issues arising and to allow onward referrals if needed.

6. STUDY PARTICIPANTS

6.1. Inclusion Criteria:

Women

- In the immediate postnatal period;
- Baby was stillborn (baby born at or after 28 weeks gestation with no signs of life [31]) or died soon after birth in the facility (early neonatal death 0-6 days[32]) during one of the two identified recruitment periods in phase 1 and 2
- Aged 18 years or over, at the time of recruitment.

Partners and family members

- Of women consented to take part in the study; they will be approached via the woman after she has agreed (a partner's unwillingness to participate will not affect the woman's continued participation)
- Aged 18 years or over, at the time of recruitment.

Health workers (midwives, nurses, doctors and support staff) and peer supporters

- Directly involved in the delivery of the study intervention **or** who provide care or services to women after stillbirth in facilities.

6.2. Exclusion Criteria:

- Unable to give consent
- Multiple birth only where one baby survived the early neonatal period

6.3. Recruitment

Individual consent will not be sought for the Perinatal Bereavement Care Group and Bereavement Champions as they will operate on a facility level, so seeking individual consent would not be possible. The peer support programme will be offered only to women experiencing a stillbirth or neonatal death at the facility who are recruited to the study in phase 2. They will be provided with details of how to access peer support by the research assistant at the initial meeting after they have agreed to participate. However, the research assistant will ensure that the woman understands that contact with the peer supporter is voluntary and they can choose not to access this component of the intervention. Consent will also be sought for data collection associated with the assessment of the feasibility of a full-scale trial, acceptability and uptake of the intervention for a sample of women, family members and staff at both facilities. Identification, screening of participants will be undertaken by appropriately trained and experienced members of the research/clinical teams and confirmation of eligibility and consenting of participants undertaken by research assistants/midwives. The study will be publicised throughout the units and information given to relevant staff in workshops held by the research team at the start of the study.

6.3.1. Women and partners/family members :

Eligible postnatal women will be identified and approached via a member of the clinical care team before discharge from the hospital who will introduce the study. If the woman is interested in receiving further information she will be asked to complete a 'Consent to Contact' form outlining her preferred time and method for contact (phone call, SMS etc) which will be posted in a sealed box for the research assistant/midwife to collect. The research assistant will contact the woman as agreed, not normally less than two weeks after discharge from hospital and provide a verbal explanation of the study supported by a written information sheet which will be available in the local language. The woman will be encouraged to discuss with family/others 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. After a period of not less than twenty-four hours, contact will be initiated (as agreed) to confirm whether or not she would like to take part. If she agrees, a convenient date/time/place will be agreed for the interview (Phase 2 only) and completion of questionnaires (phase 1 or phase 2, as applicable), the consent form will be completed at this meeting. Partners and birth partners will be approached through the woman, only after she has agreed to participate in the study following the same process outlined above. From the first contact, the research midwife will ascertain the potential participant's preferred method for initiating further contact about the study (e.g. midwife to call/SMS, participant to call/SMS). If no response is received, no more than two attempts (e.g. voice message/SMS/ email) will be made before the research midwife will assume the participant does not wish to proceed. No further contact with the participant will be made.

6.3.2. Health workers, support staff

Midwives, nurses, doctors support staff (Perinatal Bereavement Champions or members of the Perinatal Bereavment Care Group) and others (e.g peer supporters) 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. 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, a date, time and venue will be arranged for an initial meeting to confirm consent followed by a further meeting near the end of phase two for an interview

All staff who provide care or support services to women and families after a stillbirth or neonatal death, but are not directly involved in the delivery of the intervention will be informed about the research as above. At the end of phase 2, all health workers in the facility will be invited in writing to complete a short, anonymous, paper questionaire to assess awareness of the research, experiences of 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.

6.4. Participants who withdraw consent:

At the point of recruitment, all potential participants will be informed that participation in the research is voluntary and that they can withdraw consent at any time without giving any reason, without their current or future care or legal rights being affected. Data collected up to the time participant leaves the study or is lost to follow up will continue to be included in the findings, unless the participant requests that it is withdrawn. Participants will be informed that no data can be removed once the findings are anonymised and sent for publication.

7. OUTCOMES

The key outcomes for feasibility will include:

- Recruitment and retention of women in the study.
- Acceptability and uptake of the peer support component of the intervention and experiences of study processes will be explored through interviews and questionnaires from women, families, healthcare staff and others involved with the delivery of the intervention
- The characteristics of the psychological, clinical, and resource utilisation measures will be examined including estimates of parameters needed to compute an estimate of sample size for the full-scale study.

8. DATA COLLECTION, SOURCE DATA and CONFIDENTIALITY

8.1. Recruitment and retention: A **participant log** of women who fulfill the eligibility criteria, women who are invited to participate in the study, those recruited and any participants who leave the study before completion will be kept. Reasons for non-recruitment (e.g. refusal to participate, language barrier) will also be recorded. Permission will be sought to collect data on reasons for non-participation from women, partners/ family members and health workers who have provided contact details but decline to take part. During the course of the study, reasons for withdrawal and loss to follow-up will be documented.

8.2. Demographic and clinical data: 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])and obstretric history, index pregnancy 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 and access to external support up to 8 weeks postnatal. Data will be collected at recruitment and 6-8 weeks post-birth (study completion). Basic demographic data (age, ethnicity, socioeconomic status, etc) will also be collected via self-report for participating partners/family members, health workers and support staff at recruitment. Anonymised routinely collected clinical data for all births resulting in stillbirth or early neonatal death, in the included facilities during the study period will be extracted from the hospital birth registers . This will include maternal age, county of residence, occupation classification, medical and obstetric history (previous pregnancies, mode of birth, outcomes), index pregnancy data including the gestation, onset of labour, mode of birth, maternal and infant outcomes, cause of death (if known) and length of hospital stay. This will permit assessment of feasibility of comparison and assessment of the potential for selection bias in sample taking part in the research.

8.3. Acceptability of study processes and the intervention (phase2) will be captured by semi-structured face to face (or telephone) interviews with:

- Women participating in the study during phase 2 (N up to 60; up to 30 per country) 6 -8 weeks after the birth
- Partners and family members of women participating in phase 2 (N; up to 30; up to 15 per country) 6-8 weeks after the birth
- Health workers and others (e.g. parent peer supporters) involved in the delivery of the intervention (up to 30; up to 15 per country) at the end of phase 2.

Interviews will be conducted at the participant's preferred venue (home, private room in the hospital), using topic guides and audio-recorded with consent. Women and partners will be interviewed in the local language or English by a bilingual research assistant. Health

workers will be interviewed in English. Interviews will be translated where necessary and transcribed verbatim. Field notes and reflexive diaries will be completed by the research assistant as soon as possible after the interview to support interpretation of the data.

8.3.1. Uptake and additional impacts of the intervention on the practice and environment of care will be captured by:

- An **intervention log** completed by bereavement champions and peer supporters will summarise all study-related activities to determine what was done, when and by whom. This will include training, meetings, adminstration, data for peer support contacts including number of contacts, time spent , mode of support (telephone or message) with women to determine uptake of the support component of the intervention. Peer supporters will be compensated for their time in completing monthly logs with $10USD (35,000UGX) on return of each completed log.

- A short questionaire survey of health workers providing or managing care and services to women after stillbirth or neonatal death at the included facilities but not directly involved in delivering the intervention at the end of phase 2 will be conducted.

8.4. Psychological assessments:

8.4.1. Women participants will complete a questionnaire, prior to the interview, at 6-8 weeks after the birth including the following self-report tools:

- The Edinburgh Postnatal Depression Score (EPDS;) 10-item tool developed to assess depressive symptoms for postnatal use and since validated for use to identify anxiety and depressive symptoms in pregnancy[33-35].

- The Perinatal Grief scale (PGS; [36]) a 33- item measure specifically designed to assess perinatal grief

8.5. Health economics: Data will be captured to identify the key resources associated with the intervention,including:

- Human resources – the intervention log as described above will be used to identify person (bereavement champions and peer supporters) time spent attending: trainings, meetings, adminstration, travel, and support

- Equipment – a record will be kept of the number of mobile phones provided to peer support workers; health workers will be asked structured questions during their interveiw about any additional equipment required to improve care following baby loss

- Out-of-pocket expenses – women and partners/family members will be asked structured questions during their interview about any out-of-pocket expenses incurred related to the intervention e.g. cost of sending text-based messages to peer supporters, travel etc.

9. ANALYTICAL CONSIDERATIONS

9.1. Analysis

9.1.1. Recruitment and retention: Participant log data will be used to assess recruitment to targets and retention rates. A full scale trial would be considered feasible if recruitment targets were met and a rate of 70% retention achieved. Interview data will clarify possible barriers to recruitment and retention, which can be addressed in preparation for a definitive trial. If recruitment targets are not met or retention is below 70% but at least 60%, we will consider whether any identified barriers could be addressed to improve recruitment and/or retention to acceptable levels and hence make a full-scale evaluation trial potentially feasible; in this situation, the success of strategies to overcome these barriers would be expected to be assessed during an internal pilot phase.

9.1.2. Acceptabilty of a participation, the intervention and quality of implementation will be explored through analysis of the intervention log and interviews, and field notes using an inductive approach. Data will be analysed using the framework method [37], a systematic approach comprising five interlinked phases which allow the researcher to move from descriptive accounts to conceptualisation of meaning within the data. During familiarisation, the immersion in the data allows the researcher to identify an overview of main ideas or concepts. This allows the development of a draft theoretical framework. In the third stage, the draft framework is applied back to the raw data to determine fit, known as indexing, and refine as needed. The data are them summarised into thematic charts. In the final phase, data are synthesised through the process of mapping and interpretation [38]. Stages 1-4 will be conducted by two researchers, independently, before the review of the charts and confirmation of the overall interpretation and with the input of the wider research team in stage 5. This is to ensure that the key messages conveyed remain truthful to the participant's accounts; transcripts will not be returned to the participants for member-checking. Data will also help determine the appropriateness of proposed outcomes measures. Participants' views and experiences of completing questionnaires and diaries will contribute to evaluating the burden of trial assessments and inform data collection methods for the main trial. The views and experiences of parents, staff and others delivering the intervention and other professionals involved in care will be used to determine acceptability of the intervention and fidelity of the components as delivered in practice compared with those planned, including any impacts on wider services. This data will also identify any areas where further refinement of the intervention is needed.

9.1.3. Psychological assessments, and clinical data: Quantitative data will be inputted into a custom-designed SPSS database. Outcome measures will be compared descriptively, using frequencies and percentages for categorical variables and descriptive statistics including means, standard deviations, medians and ranges for numerical variables. Data from psychological tools will be compared to determine whether characteristics are comparable

across different measures. This will include a comparison between rates of missing data for different tools and their component items. Analysis will focus on the estimation of confidence intervals for differences between the groups and the estimation of variances to inform the design of the full scale trial.

11. Sample Size:

A formal power calculation is not appropriate for a feasibility study, therefore the total sample size of 80-120 women has been determined pragmatically according to the accepted criteria for feasibility studies [39].These numbers will allow implementation of the intervention in two sites and estimation of recruitment/ retention rates and uptake. Previous experience with similar nested qualitative interview studies indicates that the sample sizes indicated will be more than adequate to achieve data saturation for parents and health worker interviews [31].

12. DATA MONITORING AND QUALITY ASSURANCE

12.1. Trial management This study will be subject to the audit and monitoring regime of the sponsor, The University of Manchester. Formal monitoring via a data monitoring committee will not be undertaken during this feasibility study as the anticipated risk of harm is low. The existing NIHR Global Health Research Group for Stillbirth Prevention and Management in Sub-Saharan Africa at the University of Manchester Advisory Board chaired by Professor Matthews Mathai (Liverpool School Hygiene and Tropical Medicine) will provide technical support and advice on the conduct of the feasibility study and full trial. The Advisory Board will review the study protocol prior to commencment of the research and any amendments, receive progress updates, advise on issues arising with the study conduct and dissemination of the findings in preparation for a full trial.

The study will be managed by Professor Lavender with support from the research team and country principal investigators. A start up meeting with UK and local research teams will be held in-country (location TBC Kenya or Uganda, in Month 1). The Kenya and Uganda Study leads will be responsible for day to day co-ordination of trial activity from month 1-month 12, supported by research assistants. Meetings between the CI/UK research team and Country leads will be conducted via Zoom 2 weekly initially and at least monthly for the duration of the research. The wider research team, including all co-applicants and the Africa research leads, research assistants will meet bi-monthly via Skype to review progress and compliance with research governance.

12.2. Research Team

Professor Dame Tina Lavender: Chief Investigator responsible for overall study management, research governance, supervision of the research. Supervise training and

supervision for delivery of the intervention, qualitative and clinical analysis, interpretation, reporting and dissemination.

Dr Tracey A Mills : Co investigator, support for Chief investrigator, set up, training and supervision for delivery of the intervention, qualitative and clinical analysis, interpretation, reporting and dissemination

Professor Karina Lovell: Co investigator, lead for community engagement, support training for delivery of the intervention. Advise on analysis/ interpretation of pyschological oucomes data and design of full trial.

Dr Carol Bedwell: Co investigator, support for Chief investrigator, set up, training and supervision for delivery of the intervention, qualitative and clinical analysis, interpretation, reporting and dissemination.

Dr Chris Sutton: Co investigator, supervise analysis of the quantitative data, provide statistical advice and guidance for the design of the full trial.

Dr Elizabeth Camacho: Co investigator, supervise health economics and cost-effectiveness components, advice on design of econoomic evaluation for main trial .

Dr Lucie Byrne-Davis: Co investigator, advise on behaviour change input for training intervention development. Advise on analysis/ interpretation of pyschological oucomes data .

Prof Alexander Heazell: Co investigator, advise on obstetric aspects of the research, quantitative and clinical analysis, interpretation, reporting and dissemination.

Professor Grace Omoni: Principle Investigator Kenya, responsible for overall study management, research governance, supervision of the research in Kenya. Supervise training and supervision for delivery of the intervention, qualitative and clinical analysis, interpretation, and dissemination.

Ms Elizabeth Ayebare: Principle Investigator Uganda, responsible for overall study management, research governance, supervision of the research in Uganda. Supervise training and supervision for delivery of the intervention, qualitative and clinical analysis, interpretation, and dissemination.

Ms Claire Storey: Parent Advocate, former chair Britol SANDS (Stillbirth and Neonatal Death) lead for development and training for peer support intervention.

Ms Valentina Actis Danna: Co applicant; trial manager in Manchester responsible for day to day management of the study under the supervision of the CI. Administration of REDCap, management and analysis of quantitative data.

12.3. Safety Reporting: Adverse Event definitions and reporting

For the purposes of this study the following definitions will apply:

12.3.1. Adverse events (AE)

Definition:
Any untoward medical occurrence in a participant recruited to the study, including occurrences which are not necessarily caused by or related to the intervention[40].

For this study the following is a list of expected maternal adverse events which will be recorded but not reported:

Postnatal complications:
Anaemia defined as haemoglobin level <100 g/L postpartum [41].
Post-partum haemorrhage
New onset postpartum Hypertension
Bacterial or viral infection
Wound infection (caesarean section or perineal tear)
Urinary or faecal incontinence
Breast complications e.g. engorgement, mastitis

Psychological instruments

EPDS is a validated instrument for screening for depression and low mood (during pregnancy and the postnatal period), respectively. The EDPS is calculated by scoring each item 0-3 with maximum score of 30, score of ≥10 indicates possible depression. Item 10 relates to specific suicidal thoughts.
Further action will be taken according to the flow charts in appendix 2, if a participant has raised scores on either measure:

- ≥10 on EPDS
- Score of 1 or above on item 10 of EPDS

Raised EPDS scores will also be reported in accordance with the adverse event reporting procedures outlined for this study at 10.3.3. Any other abnormal or concerning findings arising from questionnaires will be reported by the research or research assistant to the local PI directly and in accordance with the adverse event protocol as above.

12.3.2. Serious adverse events (SAE)

Definition:
Any adverse event (see definition at 10.3.1) that:

a) results in death,
b) is life-threatening,
c) requires hospitalisation or prolongation of existing hospitalisation,
d) results in persistent or significant disability or incapacity
e) ***Or*** *is otherwise considered medically significant by Professor Dame Tina Lavender, Dr Tracey Mills or Professor Karina Lovell [40]*

The following are expected serious maternal and neonatal adverse events which will be recorded but not reported for further investigation:

Postnatal complications:
Admission to hospital for anaemia
Admission to hospital for post-partum haemorrhage
Admission to hospital for postpartum hypertension
Admission to hospital for bacterial or viral infection
Admission to hospital for wound infection (caesarean section or perineal tear)
Admission to hospital for urinary or faecal incontinence
Admission to hospital for breast complications e.g: engorgement, mastitis.

12.3.3. Recording and reporting:

Adverse events will be recorded in study documentation by the research assistant, and collated for each participant on an Adverse Event Form at the end of the study. Adverse events will be reviewed at the end of the study by the NIHR Group Advisory Board and the Sponsor.

Serious Adverse Events (other than those listed above) will be recorded on a Makerere School of Health Sciences Research and Ethics committee SAE report form and reported by the research assistant to the local PI who will report to the CI as soon as possible after becoming aware (normally within 24 hours/ 1 working day).

SAEs will be reported to the Sponsor and Research Ethics Committee (REC) if in the opinion of Professor Tina Lavender (CI), Dr Tracey Mills or Professor Karina Lovell they are:

> **Related** - that is resulted from administration of any research procedures
> AND
> **Unexpected** –that is, the type of event is not listed in the protocol as an expected event

An **SAE** meeting these criteria with be reported in writing using the Serious Adverse Event Report as soon as possible and within 15 days of the CI becoming aware of the SAE. SAEs will be reviewed by the Sponsor using their standard criteria and a specific course of action will be recommended for the study and implemented by the Investigators.

13. ETHICAL CONSIDERATIONS

Research governance approvals from the University of Manchester Research Ethics Committee, and approvals in Kenya and Uganda will be obtained before commencing research.

The study will be conducted in full conformance with principles of the "Declaration of Helsinki", Good Clinical Practice (GCP) and within the laws and regulations of the country in which the research is conducted. The death of a baby before or shortly after birth is an extremely sensitive area of maternity care with potential for women, partners, families and health workers participating in research to experience emotional distress when recalling difficult or traumatic events related to the death of their baby. However, accumulating evidence demonstrates that well-conducted research does not increase risk of harm to bereaved parents and might offer some benefits [42]. Participants may become upset or distressed during contacts with the care co-ordinator midwife, during completion of questionnaires or interviews, particularly in discussing their baby's death, care experiences, grief and current thoughts and feelings.

To ensure that study is conducted appropriately and sensitively, all recruitment processes, participant information and interview topic guides will be produced with input from our established community-engagement groups of local parents with experience of perinatal bereavement. A study-specific distress policy will be available and followed at all times, research assistants will have a midwifery or nursing background and, as experienced clinicians, will have skills to deal with distressed participants. The qualitative interviewer will be an experienced researcher with Lone Worker Training who has access to the Study Co-ordinator and Chief Investigator for advice.

14. STATEMENT OF INDEMNITY

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

15. FUNDING

This study is funded through the NIHR Global Health Research Units and Groups stream, The NIHR Global Health Research Group in Stillbirth Prevention and Management at The University of Manchester

16. PUBLICATION POLICY

The findings of the study will be published in appropriate clinical journals (e.g. BJOG, BMC Pregnancy and Childbirth) with open-access where possible; costs are available to support this. The findings will also be presented at international multidisciplinary meetings including the LAMRN conference, GLOW conference and the International Stillbirth Alliance (ISA) annual meeting. The research team has established links with stakeholders. 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 12. Participants, families, clinical staff, operational mangers and stakeholders including support groups will be invited to attend. A lay summary of findings will also be sent to all participants. Service-user members of the community engagement groups will be offered the opportunity and support to contribute to dissemination if they are willing.

These activities will ensure that potential beneficiaries can engage with the study progress and findings. The overall aim is to increase awareness of the topic, application of the findings in clinical practice and reduction of the likelihood of duplication minimising future costs and burdens to funders and health systems.

17. REFERENCES

1. Kemmis, S. and R. McTaggart, *Participatory action research*, in *Handbook of Qualitative Research* N.K. Denzin and Y.S. Lincoln, Editors. 2000, Sage: Thousand Oaks Ca. p. 567-605.
2. Blencowe, H., et al., *National, regional, and worldwide estimates of stillbirth rates in 2015, with trends from 2000: a systematic analysis.* The Lancet Global Health, 2016. **4**(2): p. e98-e108.
3. Cacciatore, J. *Psychological effects of stillbirth*. in *Seminars in Fetal and Neonatal Medicine*. 2013. Elsevier.
4. de Bernis, L., et al., *Stillbirths: ending preventable deaths by 2030.* The Lancet, 2016. **387**(10019): p. 703-716.
5. Watson, J., et al., *Pregnancy and infant loss: a survey of families' experiences in Ontario Canada.* BMC Pregnancy and Childbirth, 2019. **19**(1): p. 129.
6. Flenady, V., et al., *Stillbirths: recall to action in high-income countries.* The Lancet, 2016. **387**(10019): p. 691-702.
7. Alliance, W.R., *Respectful maternity care: the universal rights of childbearing women.* White Ribbon Alliance, 2011.
8. Kiguli, J., et al., *Weeping in silence: community experiences of stillbirths in rural eastern Uganda.* Global health action, 2015. **8**(1): p. 24011.
9. Froen, J.F., et al., *Stillbirths: why they matter.* Lancet, 2011. **377**(9774): p. 1353-66.
10. Blencowe, H., et al., *National, regional, and worldwide estimates of stillbirth rates in 2015, with trends from 2000: a systematic analysis.* Lancet Glob Health, 2016. **4**(2): p. e98-e108.
11. Cacciatore, J., *Psychological effects of stillbirth.* Semin Fetal Neonatal Med, 2013. **18**(2): p. 76-82.
12. Frøen, J.F., et al., *Stillbirths: progress and unfinished business.* The Lancet, 2016. **387**(10018): p. 574-586.
13. Homer, C.S. and P. ten Hoope-Bender, *Supporting women, families, and care providers after stillbirths.* The Lancet, 2016. **387**(10018): p. 516-517.
14. White Ribbon Alliance, *Respectful maternity care: the universal rights of the childbearing woman* White Ribbon Alliance, Editor. 2011.
15. Redshaw, M., R. Rowe, and J. Henderson, *Listening to parents after stillbirth or the death of their baby after birth*. 2014, National Perinatal Epidemiology Unit: Oxford
16. Kiguli, J., et al., *Stillbirths in sub-Saharan Africa: unspoken grief.* Lancet, 2016. **387**(10018): p. e16-8.
17. Koopmans, L., et al., *Support for mothers, fathers and families after perinatal death.* Cochrane Database Syst Rev, 2013(6): p. CD000452.
18. Flenady, V., et al., *Meeting the needs of parents after a stillbirth or neonatal death.* BJOG, 2014. **121 Suppl 4**: p. 137-40.
19. *Uganda Clinical Guidelines: National Guidelines for Management of Common Conditions*, P. Department, Editor. 2016, Ministry of Health: Kampala.
20. Dennis, C.L., *Postpartum depression peer support: maternal perceptions from a randomized controlled trial.* Int J Nurs Stud, 2010. **47**(5): p. 560-8.
21. Jones, C.C., J. Jomeen, and M. Hayter, *The impact of peer support in the context of perinatal mental illness: a meta-ethnography.* Midwifery, 2014. **30**(5): p. 491-8.
22. Boyle, F.M., et al., *Supporting parents following pregnancy loss: a cross-sectional study of telephone peer supporters.* BMC Pregnancy Childbirth, 2015. **15**: p. 291.
23. Miech, E.J., et al., *Inside help: An integrative review of champions in healthcare-related implementation.* SAGE Open Med, 2018. **6**: p. 2050312118773261.

24. Shaw, E.K., et al., *The Role of the Champion in Primary Care Change Efforts: From the State Networks of Colorado Ambulatory Practices and Partners (SNOCAP).* Journal of the American Board of Family Medicine, 2012. **25**(5): p. 676-685.
25. Craig, P., et al., *Developing and evaluating complex interventions: the new Medical Research Council guidance.* BMJ, 2008. **337**: p. a1655.
26. Waterman, H., et al., *Action research: a systematic review and guidance for assessment.* Health Technol Assess, 2001. **5**(23): p. iii-157.
27. Koshy, E., V. Koshy, and H. Waterman, *Action Research in Healthcare* 2010, London: Sage.
28. Morrison, B. and R. Lilford, *How can action research apply to health services?* Qual Health Res, 2001. **11**(4): p. 436-49.
29. Michie S., Atkins L., and W. R., *The Behaviour Change Wheel: A Guide to Developing Interventions.* . 2014, London: Silverback Publishing.
30. Bull, E.R., et al., *An organisational participatory research study of the feasibility of the behaviour change wheel to support clinical teams implementing new models of care.* BMC Health Serv Res, 2019. **19**(1): p. 97.
31. World Health Organization. *Stillbirth* 2015 [cited 2016 26/09/16]; Available from: http://www.who.int/maternal_child_adolescent/epidemiology/stillbirth/en/.
32. Organization, W.H., *Neonatal and Perinatal Mortality: Country, Regional and Global Estimates*. 2006, WHO: Geneva.
33. Cox, J.L., J.M. Holden, and R. Sagovsky, *Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale.* Br J Psychiatry, 1987. **150**: p. 782-6.
34. Murray, L. and A.D. Carothers, *The validation of the Edinburgh Post-natal Depression Scale on a community sample.* Br J Psychiatry, 1990. **157**: p. 288-90.
35. Ongeri, L., et al., *Demographic, psychosocial and clinical factors associated with postpartum depression in Kenyan women.* BMC Psychiatry, 2018. **18**(1): p. 318.
36. Potvin, L., J. Lasker, and L. Toedter, *Measuring Grief - a Short Version of the Perinatal Grief Scale.* Journal of Psychopathology and Behavioral Assessment, 1989. **11**(1): p. 29-45.
37. Richie, J. and L. Spencer, *Qualitative data analysis for applied policy research*, in *Analyzing Qualitative Data* A. Bryman and R.G. Burgess, Editors. 1994, Routledge: New York. p. 173-194.
38. Richie, J., L. Spencer, and W. O'Connor, *Analysis: Practices,Principles and Processes*, in *Qualitative Research Practice: A Guide for Social Science Students and Researchers* J. Richie and J. Lewis, Editors. 2003, Sage: London.
39. Whitehead, A.L., et al., *Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable.* Stat Methods Med Res, 2016. **25**(3): p. 1057-73.
40. Health Research Authority. *Safety and Progress Reports Table (non-CTIMPs) for UK health departments' RES version 2.1 05.06.2015*. 2015 [cited 2017 22nd August]; Available from: http://www.hra.nhs.uk/documents/2015/06/safety-progress-reports-procedural-table-non-ctimps.pdf.
41. Pavord, S., et al., *UK guidelines on the management of iron deficiency in pregnancy.* Br J Haematol, 2012. **156**(5): p. 588-600.
42. Hynson, J.L., et al., *Research with bereaved parents: a question of how not why.* Palliat Med, 2006. **20**(8): p. 805-11.
43. Haigh, C. and G. Witham. *Distress protocol for qualitative data collection* 2012 [cited 2016 26/09/16]; Available from: https://www2.mmu.ac.uk/media/mmuacuk/content/documents/rke/Advisory-Distress-Protocol.pdf.

Appendix 1: Consent to contact form

Advancing care and support for women and families after stillbirth or neonatal death in Sub-Saharan Africa: A feasibility study

Consent to contact form

Version 1 (24/07/19)

Name			
Address			
Phone number			
Preferred method of contact	***SMS/Text***	***WhatsApp***	***Voice call***
Preferred time	***Am***	***Pm***	
I agree to be contacted by a member of the research team			
Signature /fingerprint			
Date			

Appendix 2: Case Report Forms

Advancing care and support for women and families after stillbirth or neonatal death in Sub-Saharan Africa: A feasibility study (Case Report Form 1: Recruitment)

Completed by:				Participant Code:	
Date of visit:				Site Number:	
Age (years)					
Religion					
Country of birth					
County of residence		Urban		Rural	
Marital status	Single	Partner	Married	Widowed	Separated/ divorced
Employed	Full time	Part-time	Unemployed	Homemaker	
If working, occupation					
Years of schooling					
Type of death	Stillbirth	Neonatal Death		Unknown	
Date of birth of baby who died		Date of Death			
If stillbirth, type	Antenatal	Intrapartum		Unknown	
Sex of baby	Male	Female		Unknown	
Gestation of pregnanc					

y at birth (weeks and days)								
Booked for care	No					Yes		
Antenatal health complications (if yes, describe briefly)	No	Yes						
Onset of labour	None			Spontaneous			Induction	
Mode of birth	Normal birth		Vacuum/ forceps			Caesarean section (general anaesthetic)		Caesarean section (spinal anaesthetic)
Birth weight								
Admission to SCBU/NNU	No					Yes		
Reason for stillbirth or neonatal death (if known)	Small for gestational age	Obstructed labour	Ante/intrapartum haemorrhage	Maternal hypertension/ pre-eclampsia /eclampsia		Infection / preterm labour	Cord accidents / cord prolapse	Unknown	Other
Post-mortem performed	No			Yes			Unknown	
Length of hospital/ facility stay after birth (days)								
Postnatal health complications	No	Yes	Anaemia	Infection		Fistula	Mental health issue	Other
Number		No of living			Previous		If yes, please give cause if	

of previous pregnancies		children		stillbirth/ neonatal death	known

MANCHESTER 1824
The University of Manchester

NIHR Global Health Research Group
on Stillbirth Prevention and Management in Sub-Saharan Africa
at The University of Manchester

Advancing care and support for women and families after stillbirth or neonatal death in Sub-Saharan Africa: A feasibility study (Case Report Form 2: Follow up)

Completed by:				Participant Code:	
Date of visit:				Site Number:	
Postnatal follow up visits (Since hospital discharge)	Date	Postnatal day	Where (hospital, community clinic, home visit)	Which health worker? (Doctor, midwife, nurse, other please state title)	
Unplanned/urgent postnatal contacts	Date	Place attended		Reason/outcome	
Postnatal hospital admissions	Date admitted	Date discharged		Reason for admission	Outcome
Other support used since hospital discharge (support groups,	Yes			No	
	Provider	Place attended, website or social media if		How often?	

websites,				online			
Any postnatal health complications (e.g obstetric fistula, infection psychological complication)	No	Yes	Anaemia	Infection	Fistula	Mental health issue	Other
Employment	Returned		Planning to return (give dates)		Not planning to return	Unemployed/homemaker	

Appendix 3: Demographic questionnaires

Advancing care and support for women and families after stillbirth or neonatal death in Sub-Saharan Africa: A feasibility study

Demographic questionnaire: Peer supportors V 1 (22/05/19)

Demographic questionnaire: Peer supporters				Participant Code
Age (years)				
Previous baby death (and number if more than 1)	Stillbirth	Neonatal death	Prefer not to say	
Time since most recent baby death				
No. of living children				
Employed	Full time	Part Time	Unemployed	Homemaker
Occupation if working				

Advancing care and support for women and families after stillbirth or neonatal death in Sub-Saharan Africa: A feasibility study

Demographic questionnaire: Health workers V1 (22/05/19)

Demographic questionnaire: Health workers				Participant Code
Gender	Female	Male		
Age (years)				
Job title	Nurse-midwife	Midwife	Doctor	Counsellor
Main area of work				
Time since qualification (years/months)				
Highest educational qualification	Certificate/ diploma	Degree	Postgraduate degree	Other
Other please give details				
Personal /family experience of pregnancy loss/perinatal death	No	Yes	Prefer not to answer	
Any pre or post registration education or training in stillbirth/bereavement care?	No	Yes* If yes please explain briefly what this was below	Unsure	
Details if yes				

Care and support after stillbirth in Kenya and Uganda
Version 2 (06/12/17)
Demographics questionnaire: Partners

Demographic questionnaire: Partners					Participant Code
Age (years)					
Religion					
Country of birth					
County of residence		Urban			Rural
Marital status	Single	Partner	Married	Widowed	Separated /divorced
Employed	Full time		Part-time		No
If working, occupation					
Previous baby stillborn or neonatal death					
No of living children					

Appendix 4: Health worker survey- Version 1.1(12/05/19)

Advancing care and support for women and families after stillbirth or neonatal death in Sub-Saharan Africa: A feasibility study

Staff Survey

Thank you for taking the time to complete this questionnaire, there are no right or wrong answers we want to know your experiences and opinions: Please read the questions carefully and record your responses in the space provided, please continue on the back of the sheet if required.

Once you have completed the questionnaire please return in the box provided in your area of work.

What is your age?				
What is your job role				
What is your main area of work?	Maternity: Labour ward	Maternity: Antenatal/postnatal ward	Maternity: Antenatal clinic	
	Maternity: Rotational (work in all areas)	Neonatal Unit/ Special Care	Other: Please specify	
How long have you been qualified (years/months)				
What is your	Certificate/	Degree	Postgraduate	Other

highest level of education	diploma		degree	
Are you aware of the Perinatal Bereavement Care Group which has recently been introduced in your facility?				
Yes		No		Not sure
Are you aware of the Perinatal Bereavement Care Champions in your area of work?				
Yes		No		Not Sure
Are you aware of any changes to the care provided/or how care is provided for women whose baby died before, during or soon after birth in your facility the last 6 months? Please describe below:				
Could anything else be done to improve the care provided in your facility for bereaved women and families in the future? Please describe below:				

Thank you for taking the time to complete this questionnaire.
If you wish to be entered in the Draw for one of 2 X $25 USD prizes, please provide a contact email address below:

Email: ……

Advancing care and support for women and families after stillbirth or neonatal death in Sub-Saharan Africa: A feasibility study

Appendix 5: Distress Policy

MANCHESTER 1824
The University of Manchester

NIHR Global Health Research Group
on Stillbirth Prevention and Management in Sub-Saharan Africa
at The University of Manchester

Distress policy A - Participant distress (Adapted from and Witham[43])

Distress

- Participant indicates that they are experiencing high levels of stress, anxiety or emotional distress
- Participant exhibits signs suggestive of excessive stress, anxiety or emotional distress e.g uncontrolled crying, shaking.

Response

- **Pause interview**
- Midwife researcher to offer immediate support
- Assess mental state ASK:
  - Tell me what thoughts you are having?
  - Tell me how you are feeling right now?
  - Do you feel able to go on with your day?
  - Do you feel safe ?

Review

- If participant feels able to continue, resume interview
- If not go to stage 2

Stage 2 Response

- **Stop interview**
- Encourage participant to contact family member, friend or healthcare provider, work colleague or supervisor (health professionals) OR
- Offer for an member of the research team to do so

Follow up

- Follow up participant with a call (if consents)
- Encourage participant to call member of research team if experiences increaseed distress in the days following interview/focus group
- Consider referral to Counselling Service for further support and guidance

Appendix 6: Peer support Log

Advancing care and support for women and families after stillbirth or neonatal death in Sub-Saharan Africa: A feasibility study: Peer Support Log

Completed By Start Date					Participant code: Site No:
Date	**Time**	**Contact No**	**Mode of contact Telephone/Message**	**Duration**	**Notes**

Completed By					Participant code:
Start Date					Site No:
Date	**Time**	**Contact No**	**Mode of contact Telephone/Message**	**Duration**	**Notes**

Completed By Start Date					Participant code: Site No:
Date	**Time**	**Contact No**	**Mode of contact Telephone/Message**	**Duration**	**Notes**

Appendix 7: Questionnaire (English version)

Advancing care and support for women and families after stillbirth or neonatal death in Sub-Saharan Africa: A feasibility study

Questionnaire (English version)

Date:	Participant No
	Site No

Thank you for taking the time to complete this questionnaire about how you are feeling

- There are no right or wrong answers
- Some of the questions may seem repetitive but this is intentional.
- Please read the questions carefully and record your responses as requested.

If you need any help completing the questionnaires in the booklet, please contact XXXXXXX (Study Research Assistant). If you are worried about the way that you are feeling please speak to XXXX (study research assistant) or your local community health worker.

Perinatal Greif Scale

PRESENT THOUGHTS AND FEELINGS ABOUT YOUR LOSS

Each of the items is a statement of thoughts and feelings which some people have concerning a loss such as yours. There is no 'right' or 'wrong' response to these statements. For each item, circle the number which best indicated the extent to which you agree or disagree with it at the present time. If you are not certain, use the "neither" category. Please try to use this category only when you truly have no opinion.

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree
1. I feel depressed.	1	2	3	4	5
2. I find it hard to get along with certain people.	1	2	3	4	5
3. I feel empty inside.	1	2	3	4	5
4. I can't keep up with my normal activities	1	2	3	4	5
5. I feel it would be helpful to talk about the baby.	1	2	3	4	5
6. I am grieving for the baby	1	2	3	4	5
7. I am frightened.	1	2	3	4	5
8. I have considered suicide since the loss.	1	2	3	4	5
9. I take medicine to calm me down	1	2	3	4	5
10. I very much miss the baby.	1	2	3	4	5
11. I feel I have adjusted well to the loss.	1	2	3	4	5
12. It is painful to recall memories of the loss.	1	2	3	4	5
13. I get upset when I think about the baby.	1	2	3	4	5
14. I cry when I think about the baby.	1	2	3	4	5
15. I feel guilty when I think about the baby.	1	2	3	4	5
16. I feel physically ill when I think about the baby.	1	2	3	4	5
17. I feel unprotected in a dangerous world since my baby died.	1	2	3	4	5
18. I try to laugh, but nothing seems funny anymore.	1	2	3	4	5
19. Time passes so slowly since the baby died.	1	2	3	4	5
20. The best part of me	1	2	3	4	5

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree
died with the baby.					
21. I have let people down since the baby died.	1	2	3	4	5
22. I feel worthless since my baby died.	1	2	3	4	5
23. I blame myself for the baby's death.	1	2	3	4	5
24. I get angry at my friends and relatives more than I should.	1	2	3	4	5
25. Sometimes I feel like I need a professional counsellor to help me get my life back together again.	1	2	3	4	5
26. I feel as though I'm just existing and not really living since my baby died.	1	2	3	4	5
27. I feel so lonely since the baby died.	1	2	3	4	5
28. I feel somewhat apart and remote, even among friends.	1	2	3	4	5
29. It's safer not to love.	1	2	3	4	5
30. I find it difficult to make decisions since the baby died.	1	2	3	4	5
31. I worry about what my future will be like.	1	2	3	4	5
32. Being a bereaved parent means being a "less important person".	1	2	3	4	5
33. It feels great to be alive.	1	2	3	4	5

Edinburgh Postnatal Depression Scale

For each question please tick the answer which comes closest to how you have been feeling <u>in the last 7 days</u>, not just how you are feeling today	
1. I have been able to laugh and see the funny side of things: ☐ As much as I always could ☐ Not quite as much now ☐ Definitely not so much now ☐ Not at all	**6. Things have been getting on top of me:** ☐Yes, most of the time I haven't been able to cope at all ☐Yes, sometimes I haven't been coping as well as usual ☐No, most of the time I have coped quite well ☐No, I have been coping as well as ever
2. I have looked forward with enjoyment to things: ☐ As much as I ever did ☐ Rather less than I used to ☐Definitely less than I used to ☐Hardly at all	**7. I have been so unhappy that I have had difficulty sleeping:** ☐Yes, most of the time ☐Yes, sometimes ☐Not very often ☐No, not at all
3. I have blamed myself unnecessarily when things went wrong: ☐Yes, most of the time ☐Yes, some of the time ☐Not very often ☐No, never	**8. I have felt sad or miserable:** ☐Yes, most of the time ☐Yes, quite often ☐Not very often ☐No, not at all
4. I have been anxious or worried for no good reason: ☐No, not at all ☐Hardly ever ☐Yes, sometimes ☐Yes, very often	**9. I have been so unhappy that I have been crying:** ☐Yes, most of the time ☐Yes, quite often ☐Only occasionally ☐No, never
5. I have felt scared or panicky for no very good reason: ☐Yes, quite a lot ☐Yes, sometimes ☐No, not much ☐No, not at all	**10. The thought of harming myself has occurred to me:** ☐Yes, quite often ☐Sometimes ☐Hardly ever ☐Never

Thank you for completing this questionnaire

If you are worried about the way that you are feeling please speak to XXXX (study research assistant) or your local community health worker.

Appendix 8: Questionnaire (Luganda version)

MANCHESTER 1824
The University of Manchester

NIHR Global Health Research Group
on Stillbirth Prevention and Management in Sub-Saharan Africa
at The University of Manchester

Okutumbula endabilira n'obuyambi obuweebwa abakyaala n'abomu maka gaabwe oluvannyuma lwo'kufiirwa omwana mu lubuto oba mu mweezi gumu nga yaakazaalibwa mu kitundi kya Afirika ekiri wansi w'eddungu Sahara: Okunoonyereza okukakasa oba kisoboka.

Ekiwandiiko ekiliko ebibuuzo

Date:	Participant No
	Site No

Webale nnyo kutwaala budde n'ojjuzaamu ebibuuzo bino ebikwatagana ku ngeri gy'owuliramu

- Tewali kuddamu kutuufu oba kukyaamu.
- Ebibuuzo ebimu bilabika nga ebiddiddwaamu naye kino tukigendereddde.
- Tukusaba osome ebibuuzo bino n'obwegenderevu era owandiike eky'okuddamu kyo nga bw'osabiddwa.

Bw'oba weetaaze okuyambibwaako mu kujjuza ebiuuzo mu kiwandiiko kino, tukusaba otuukilire omusawo (XXXXX) ayamabako mu kunonyereza kuno. Bw'oba weralikilidde olw'engeri gy'owuliramu, tukusaba oyogere ko n'omusawo (XXXXX) ayambako mu kunonyereza kuno oba oyogere n'omusawo ow'okukyaalo kyo.

Minzaani epima ennyiike

Engeri gy'owuliramu kati oluvannyuma lw'okifiirwa

Buli kibuuzo kyoogera ku bilowoozo n'engeri abantu abamu gyebawuliramu nga batuukidwaako ekizibu eky'okufiirwa nga kino ekikyo. Tewali kuddamu kutuufu oba

kukyaamu. Tukusaba oteeke enkulungo ku nnamba essinga okulaga engeri gy'okkiriziganya oba gy'otakkirizaganya na bigambo byoogeddwa mu kiseera kino. Bw'oba tomanyi ky'akuddamu, kozesa eky'okuddamu ekya "silina wengwa", tukusaba okozese eky'okuddamu kino singa obeera ddala tolina ndowooza ku bigambo ebyo.

	Nzikkiriza nnyo n'amaanyi	**Nzikiriza**	**Silina wengwa**	**Ssikkiriza**	**Ssikkiriza yadde n'akamu**
1. Mpulira nnina ennyiike	1	2	3	4	5
2. Kinzibuwalira okukwatagana n'abantu abamu	1	2	3	4	5
3. Mpulira obwennyamivu	1	2	3	4	5
4. Sikyasobola kukola milimu gyange egyabulijjo nga bwennali	1	2	3	4	5
5. Mpulira nga kyandinnyambye eky'okwogera ku mwana wange.	1	2	3	4	5
6. Nkungubagira omwana wange	1	2	3	4	5
7. Mpulira nga ntidde	1	2	3	4	5
8. Ndowoozezza ku ky'okwetta okuva lwennafiirwa.	1	2	3	4	5
9. Mmira eddagala okusobola okunzikakkanya	1	2	3	4	5
10. Omwana wange mmusubwa nnyo.	1	2	3	4	5
11. Mpulira nga ngenda mmanyiira embeera oluvannyuma lw'okuviirwako omwana	1	2	3	4	5

	Nzikkiriza nnyo n'amaanyi	Nzikiriza	Silina wengwa	Ssikkiriza	Ssikkiriza yadde n'akamu
12. Kiluma okujjukira ebyabaawo mu kiseera ey'okufiirwa.	1	2	3	4	5
13. Bwe ndowooza ku mwana, mpulira obusungu	1	2	3	4	5
14. Bwe mmulowoozako nkaaba	1	2	3	4	5
15. Bwe ndowooza ku mwana, mpulira nga kinnumiriza.	1	2	3	4	5
16. Bwe ndowooza ku mwana, mpulira obukosefu	1	2	3	4	5
17. Mpulira nga atakyaalina bukuumi mu nsi eno okuva lweyafa.	1	2	3	4	5
18. Ngezaako okuseka naye tewakyaali kinsesa	1	2	3	4	5
19. Obudde tebugenda okuva omwana wange lweyafa.	1	2	3	4	5
20. Ekitundu ekisinga obulungi ku mubiri gwange kyaagenda n'omwana.	1	2	3	4	5
21. Namalamu abantu amanyi okuva omwana lweyafa.	1	2	3	4	5
22. Mpulira nga silina muwendo okuva lwe yafa.	1	2	3	4	5
23. Neenenya olw'okufa kw'omwana.	1	2	3	4	5

	Nzikkiriza nnyo n'amaanyi	Nzikiriza	Silina wengwa	Ssikkiriza	Ssikkiriza yadde n'akamu
24. Nyiizibwa nnyo ab'emikwano n'ab'enganda okusinga nga bwennali.	1	2	3	4	5
25. Ebiseera ebimu mpulira nga neetaaga omuwi w'amagezi omutendeke okunnyamba okukomyaawo obulamu bwange	1	2	3	4	5
26. Okuva lwe yafa, mpulira nga aliwo obubeezi, nga silina bulamu.	1	2	3	4	5
27. Mpulira nga ndi nzekka okuva lwe yafa.	1	2	3	4	5
28. Mpulira nga eyeeyawudde ku mikwano jange. (Mpulira nga ndi nzekka)	1	2	3	4	5
29. Kisingako obutabeera mu mukwano.	1	2	3	4	5
30. Kinzibuwalira okukola okusalawo okuva omwana lwe yafa.	1	2	3	4	5
31. Nneelarikirira engeri ebiseera byange eby'omumaaso bwebinaabeera.	1	2	3	4	5
32. Okubeera omuzadde afiiriddwa kitegeeza nti toli wa mugaso.	1	2	3	4	5

	Nzikkiriza nnyo n'amaanyi	Nzikiriza	Silina wengwa	Ssikkiriza	Ssikkiriza yadde n'akamu
33. Kiwulikika bulungi okubeera omulamu.	1	2	3	4	5

EDINBURGH POSTNATAL DEPRESSION SCALE

Tukusaba okebere ekyokuddamu ekikwatagana ku ngeri gyeweewuliddemu ennaku musanvu (7) eziyise, wabula ssi nga bwewewuliramu olwaleero	
1. Mbadde nsobola okuseka n'okulaba ebisesa mu bintu □ Nnyo nga bwembadde nsobola/ Nyo ngabwekisoboka □ Ssi nnyo ddala kati □ Kilabikirawo nti ssi kyingi nnyo kati □ Nedda nakatono	6. Ebintu bibadde binsukkirirako □ Yee, ebiseera ebisinga mbadde ssisobola kubigumira nakatono □ Yee, ebiseera ebimu mbadde ssibigumira bulungi nga bulijjo □ Nedda, ebiseera ebisinga mbigumidde bulungiko □ Nedda, mbadde mbigumira bulungi nga okuva edda
2. Mbadde nduubilira okunyumirwa ebintu □ Nnyo nga bwennali nsobodde □ Wabula kitono okusiingako bwennali □ Kirabikirawo nti kitono okusiinga bwennali □ Kitono nnyo ddala	**7.** Mbadde ssili musanyufu nnyo okutuuka n'okubulwa otulo □ Yee, ebiseera ebisinga □ Yee, ebiseera ebimu □ Nedda emirundi ssi mingi □ Nedda, tekibaddewo yadde
3. Nnenenyezza ekitasaana nga ebintu tebigenze bulungi □ Yee, ekiseera kyonna □ Yee, ebiseera ebimu □ Nedda, emirundi ssi mingi □ Nedda, tekibangawo	**8.** Mpulidde ennyiike/ ennaku □ Yee, ebiseera ebisinga □ Yee, emirundi mingi ko □ Emirundi ssi mingi □ Nedda tekibaddewo yadde
4. Mbadde mweralikirivu awatali nsonga	**9.** Mbadde ssili musanyufu nnyo okutuuka

yamaanyi. □ Nedda, nedda nakatono □ Kitono nnyo ddala □ Yee, ebiseera ebimu □ Yee, emirundi mingi	n'okuba nga mbaade nkaaba □ Yee, ebiseera ebisiinga □ Yee, emirundi mingi ko □ Lumu na lumu □ Nedda, tekibangawo
5. Mbadde mpulira okutya/ okupapirira awatali nsonga yamaanyi nnyo □ Yee, kungi ko □ Yee, ebiseera ebimu □ Nedda ssi nnyo □ Nedda tewali nakatono	**10.** Ekirowoozo ky'okweetuusako obulabe kyantuseeko □ Yee, emirundi mingi ko □ Ebiseera ebimu □ Kitno nnyo ddala □ Tekibangawo

Webale nnyo okujjuza ebibuuzo bino

Bw'oba weelalikiridde olw'engeri gy'owuliramu, tukusaba oyogereko ne XXXXX (ayambako mu kunonyereza) oba omusawo w'okukyaalo kyo.

TRANSLATION AND BACK TRANSLATION OF THE PERINATAL GRIEF SCALE

PGS item	Translation from English to Luganda	Back translation with two translators	Final translation into Luganda by the entire team
1. I feel depressed.	Mpulira ndi mwennyamivu	*I feel sorrowful*	Mpulira nnina ennyiike
2. I find it hard to get along with certain people.	Kinzibuwalira okukwatagana n'abantu abamu	*I find it hard to collaborate with some people*	Kinzibuwalira okukwatagana n'abantu abamu
3. I feel empty inside.	Mpulira nga nnina ekituli munda	*I feel worthless*	Mpulira obwennyamivu
4. I can't keep up with my normal activities	Sikyasobola kukola milimu gyange egyabulijjo nga bwennali	*I cannot meet up to the standards of my normal work*	Sikyasobola kukola milimu gyange egyabulijjo nga bwennali
5. I feel it would be helpful to talk about the baby.	Mpulira ekyeetaago eky'okwogera ku mwana wange.	*I feel the need to talk about my baby*	Mpulira nga kyandinnyambye eky'okwogera ku mwana wange.
6. I am grieving for the baby	Nkungubagira omwana wange	*I mourn for my baby*	Nkungubagira omwana wange
7. I am frightened.	Mpulira nga ntidde	*I feel scared*	Mpulira nga ntidde
8. I have considered suicide since the loss.	Ndowoozezza ku ky'okwetta okuva lwennafiirwa.	*I have thought about suicide since the loss*	Ndowoozezza ku ky'okwetta okuva lwennafiirwa.
9. I take medicine to calm me down	Mmira eddagala okusobola okuwulira obulunji	*I take some anti-depressants*	Mmira eddagala okusobola okunzikakkanya
10. I very much miss the baby.	Omwana wange mmusubwa nnyo.	*I miss my baby so much*	Omwana wange mmusubwa nnyo.
11. I feel I have adjusted well to the loss.	Mpulira nga mmanyidde bulungi embeera y'okufiirwa.	*I feel that I am getting used to the situation of the loss*	Mpulira nga ngenda mmanyiira embeera oluvannyuma lw'okuviirwako omwana
12. It is painful to recall memories of the loss.	Kiluma okujjukira ebyabaawo mu kiseera ey'okufiirwa.	*It hurts to remember what happened during the loss*	Kiluma okujjukira ebyabaawo mu kiseera ey'okufiirwa.

13. I get upset when I think about the baby.	Bwe ndowooza ku mwana, mpulira obusungu	*When I think about the baby, I get angry*	Bwe ndowooza ku mwana, mpulira obusungu
14. I cry when I think about the baby.	Bwe mmulowoozako nga nkaaba	*When I think about it, I cry*	Bwe mmulowoozako nkaaba
15. I feel guilty when I think about the baby.	Bwe ndowooza ku mwana, mpulira nga kinnumiriza.	*When I think about the baby, I feel guilty*	Bwe ndowooza ku mwana, mpulira nga kinnumiriza.
16. I feel physically ill when I think about the baby.	Bwe ndowooza ku mwana, mpulira nga ndi muyi.	*When I think about the baby, I feel sick*	Bwe ndowooza ku mwana, mpulira obukosefu
17. I feel unprotected in a dangerous world since my baby died.	Mpulira nga silina bukuumi bwonna mu nsi eno embi okuva bweyafa.	*I feel very unprotected in this ugly world since it died*	Mpulira nga atakyaalina bukuumi mu nsi eno okuva lweyafa.
18. I try to laugh, but nothing seems funny anymore.	Ngezaako okuseka naye tewakyaali kintu kyonna kilabika kunsesa.	*I try to smile but there seems to be nothing more to make me smile*	Ngezaako okuseka naye tewakyaali kinsesa
19. Time passes so slowly since the baby died.	Obudde butambula mpola nnyo okuva omwana lweyafa.	*Time moves slowly since the baby died*	Obudde tebugenda okuva omwana wange lweyafa.
20. The best part of me died with the baby.	Ekitundu ekisinga obulungi ku mubiri gwange kyaafa n'omwana.	*The better part of my life died along with the baby*	Ekitundu ekisinga obulungi ku mubiri gwange kyaagenda n'omwana.
21. I have let people down since the baby died.	Njabulidde abantu (Mbamazeemu amanyi) okuva omwana lwe yafa.	*I have let down people (I have disappointed them) since the baby died*	Namalamu abantu amanyi okuva omwana lweyafa.
22. I feel worthless since my baby died.	Mpulira nga silina muwendo okuva lwe yafa.	*I feel that I don't have any value since the baby died*	Mpulira nga silina muwendo okuva lwe yafa.

23. I blame myself for the baby's death.	Neenenya olw'okufa kw'omwana.	*I blame myself for the death of my baby*	Neenenya olw'okufa kw'omwana.
24. I get angry at my friends and relatives more than I should.	Nyiizibwa nnyo ab'emikwano n'ab'enganda okusinga nga bwennina okuba.	*I am irritated by my friends and relatives more than it should be*	Nyiizibwa nnyo ab'emikwano n'ab'enganda okusinga nga bwennali.
25. Sometimes I feel like I need a professional counsellor to help me get my life back together again.	Ebiseera ebimu mpulira nga neetaaga omuwi w'amagezi omutendeke okunnyamba okuzza wamu obulamu bwange	*Sometimes I feel like I need a counsellor to help me put my life back to order*	Ebiseera ebimu mpulira nga neetaaga omuwi w'amagezi omutendeke okunnyamba okukomyaawo obulamu bwange
26. I feel as though I'm just existing and not really living since my baby died.	Okuva lwe yafa, mpulira nga aliwo obubeezi, nga silina bulamu.	*Since the baby died, I feel like am just there, as if I don't have life*	Okuva lwe yafa, mpulira nga aliwo obubeezi, nga silina bulamu.
27. I feel so lonely since the baby died.	Mpulira nga ndi nzekka okuva lwe yafa.	*I feel lonely since the baby died*	Mpulira nga ndi nzekka okuva lwe yafa.
28. I feel somewhat apart and remote, even among friends.	Mpulira nga eyeyawuddemu kko era nga ali ewala ennyo ne bwe mbeera mu mikwano jange.	*I feel like distant like am very far even when I am with my friends*	Mpulira nga eyeeyawudde ku mikwano jange. (Mpulira nga ndi nzekka)
29. It's safer not to love.	Kisingako obutabeera mu mukwano.	*It's better not to be in love*	Kisingako obutabeera mu mukwano.
30. I find it difficult to make decisions since the baby died.	Kinzibuwalira okukola okusalawo okuva omwana lwe yafa.	*It's hard for me to make a decision since the baby died*	Kinzibuwalira okukola okusalawo okuva omwana lwe yafa.

31. I worry about what my future will be like.	Nneelarikirira engeri ebiseera byange eby'omumaaso bwebinaabeera.	*I worry about how my future will be*	Nneelarikirira engeri ebiseera byange eby'omumaaso bwebinaabeera.
32. Being a bereaved parent means being a "less important person".	Okubeera omuzadde afiiriddwa kitegeeza nti "tolina mwaasirizi".	*To be a mother who has lost a baby means that "you are needy"*	Okubeera omuzadde afiiriddwa kitegeeza nti toli wa mugaso.
33. It feels great to be alive.	Kiwulikika bulungi okubeera omulamu.	*It sounds good to be alive*	Kiwulikika bulungi okubeera omulamu.

TRANSLATION AND BACK TRANSLATION OF EDINBURG POSTNATAL DEPRESSION SCALE

EPDS item	**Translation from English to Luganda**	**Back translation with two translators**	**Final translation into Luganda by the entire team**
I have been able to laugh and see the funny side of things.	Mbadde nsobola okusekan'okulaba ebisesa mu bintu	*I could manage to laugh and see good in some things*	Mbadde nsobola okusekan'okulaba ebisesa mu bintu
I have looked forward with enjoyment to things.	Mbadde nduubilira okunyumirwa ebintu	*I have been pursuing to enjoy things*	Mbadde nduubilira okunyumirwa ebintu
I have blamed myself unnecessarily when things went wrong.	Nnenenyezza ekitasaana nga ebintu tebigenze bulungi	*I have blamed myself for no reason when things don't go well*	Nnenenyezza ekitasaana nga ebintu tebigenze bulungi
I have been anxious or worried for no good reason	Mbadde mweralikirivu awatalinsonga etegeerekeka.	*I have been worried for no valid reason*	Mbadde mweralikirivu awatalinsonga yamaanyi.
I have felt scared or panicky for no very good reason	Mbadde mpulira okutya/ okupapirira awatalinsonga etegeerekeka	*I would get scared/be in hasty for no valid reason*	Mbadde mpulira okutya/ okupapirira awatalinsonga yamaanyi nnyo
Things have been getting top of me	Ebintu bibadde binsukkako	*I was overwhelmed*	Ebintu bibadde binsukkirirako
I have been so unhappy that I have had difficulty sleeping	Mbadde ssili musanyufu nnyo okutuuka n'okufuna obuzibu mukwebaka	*I haven't been so happy that I could find it hard to sleep*	Mbadde ssili musanyufu nnyo okutuuka n'okubulwa otulo
I have felt sad or miserable	Mpulidde ennyiike/ ennaku	*I have felt sorrowful/sad*	Mpulidde ennaku/enyiike
I have been so unhappy that I have been crying	Mbadde ssili musanyufu nnyo okutuuka n'okubanga mbadde nkaaba	*I haven't been very happy to the extent that I have been crying*	Mbadde ssili musanyufu nnyo okutuuka n'okubanga mbadde nkaaba
The thought of	Ekirowoozo	*The thought of*	Ekirowoozo

harming myself has occurred to me	ky'okweetuusako obulabe kyantuseeko	*harming myself has ever come across my mind*	ky'okweetuusako obulabe kyantuseeko

Edinburgh Postnatal Depression Scale[1] (EPDS)

Postpartum depression is the most common complication of childbearing.[2] The 10-question Edinburgh Postnatal Depression Scale (EPDS) is a valuable and efficient way of identifying patients at risk for "perinatal" depression. The EPDS is easy to administer and has proven to be an effective screening tool.

Mothers who score above 13 are likely to be suffering from a depressive illness of varying severity. The EPDS score should not override clinical judgment. A careful clinical assessment should be carried out to confirm the diagnosis. The scale indicates how the mother has felt ***during the previous week***. In doubtful cases it may be useful to repeat the tool after 2 weeks. The scale will not detect mothers with anxiety neuroses, phobias or personality disorders.

Women with postpartum depression need not feel alone. They may find useful information on the web sites of the National Women's Health Information Center <www.4women.gov> and from groups such as Postpartum Support International <www.chss.iup.edu/postpartum> and Depression after Delivery <www.depressionafterdelivery.com>.

SCORING

QUESTIONS 1, 2, & 4 (without an *)
Are scored 0, 1, 2 or 3 with top box scored as 0 and the bottom box scored as 3.

QUESTIONS 3, 5-10 (marked with an *)
Are reverse scored, with the top box scored as a 3 and the bottom box scored as 0.

Maximum score: 30
Possible Depression: 10 or greater
Always look at item 10 (suicidal thoughts)

Instructions for using the Edinburgh Postnatal Depression Scale:

1. The mother is asked to check the response that comes closest to how she has been feeling in the previous 7 days.
2. All the items must be completed.
3. Care should be taken to avoid the possibility of the mother discussing her answers with others. (Answers come from the mother or pregnant woman.)
4. The mother should complete the scale herself, unless she has limited English or has difficulty with reading.

[1]Source: Cox, J.L., Holden, J.M., and Sagovsky, R. 1987. Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal Depression Scale. *British Journal of Psychiatry* 150:782-786.

[2]Source: K. L. Wisner, B. L. Parry, C. M. Piontek, Postpartum Depression N Engl J Med vol. 347, No 3, July 18, 2002, 194-199

Appendix 9: Topic Guides (English versions)

Advancing care and support for women and families after stillbirth or neonatal death in Sub-Saharan Africa: A feasibility study

Interview Topic Guide

(Version 1, 22/05/19: Family member)

Interviews with family members to explore experiences of care and support after stillbirth or neonatal death and the study intervention in Kenya and Uganda

1. Introduction, setting ground rules:

Introduce self, thank participant for taking part and confirm agrees to interview taking place. Ensure environment is comfortable. Discuss the following issues:

- Review the nature and purpose of the research.
- No right or wrong answers, aim to understand experiences.
- Confidentiality, use of data.
- Explain the use of data recorder, transcription, use of pseudonym (invite to choose), use of verbatim quotes, will be taking field notes.
- Researcher aware that discussion might bring up difficult memories, explain can decline to answer any question or prompt; can ask to stop at any time if feels need to.
- Expected duration of interview.
- Check consent form signed, complete case report form and psychological questionnaire.
- Ask if any questions.

Check recorder working

Introduce and switch on tape recorder

General prompts

- Allow participant to respond uninterrupted and use open prompts if required to explore aspects of their experiences in depth.
- Can you tell me more about XXX?', 'What makes you say XXX? How did XX make you feel?

1. **Opening questions:**

It would be helpful if you could start by telling me something about your family member, her children and what you know about her baby who died?

Allow them to describe what happened, when and how, uninterrupted.

- *Establish their relationship with the woman.*
- *Establish the sex of the baby and describe following the participants lead if unsure.*
- *Allow participant to describe what happened, when and how*

2. Care in facilities:

Can you tell us about the care your family member received whilst they were in the hospital/facility after the birth?

- *Explore if they know how they were told about the death, other communication with staff in facilities.*
- *Did the woman / partner see/hold they baby, how was this managed?*
  - *Explore awareness of the intervention e.g. bereavement champions, any specific aspects of care which were helpful.*
  - *Did they visit the facility, how was this experience?*

3. Going home:

Can you tell me about how your family member has been feeling and coping with the death of the baby since she came home?

How are you feeling?

How did others respond to your family member following the death of her baby?

- *Explore – experiences wither partner/ father of the baby, family, and friends?*

Has your family member had any contacts with health workers since she came home?

- *Any routine follow-up, explore advice and support*
- *Explore any health problems that they know about after the birth, access to care, how health issues impacted on coping with the death of the baby.*

Explore awareness/access/uptake of the peer support component?

- *Were they aware, do they know whether the family member has used this.*
- *Explore potential barriers to uptake (lack of access to phone, costs of calls, texts)*

4. ***Present situation***

   Are you aware of any particular helped your family member cope with the baby's death?

   - *Explore cultural, religious beliefs and traditions.*
   - *Explore any other sources of support.*

   What do you think could have improved their experience?

   - *Explore any factors identified, including aspects of care or support in facilities or after discharge, including the intervention that might be altered or improved.*

5. ***This research***

   How do you feel about participating in this research?

   How do you feel about participating in this interview?

   Is there anything else you might want to add?

At the close of the interview briefly summarise the main points to confirm interpretation with the participant. Ask if they wish to expand any responses or add anything else to the discussion. Thank the participants for their time, offer $10 USD Kenya /Uganda local equivalent.

Ask how they feel after talking about these experiences, do they want you to contact anyone? Family, friend, health worker?

Ensure participant has contact details for the local research team should they wish to discuss any aspect of the study. Complete reflexive diary/field notes

Advancing care and support for women and families after stillbirth or neonatal death in Sub-Saharan Africa: A feasibility study

Interview Topic Guide

(Version 1, 22/05/19: Health workers delivering the intervention)

Interviews with health workers explore experiences of care and support after stillbirth or neonatal death and delivery of the intervention in Kenya and Uganda:

1. Introduction, setting ground rules:

Introduce self, thank participant for taking part and confirm agrees to interview taking place. Ensure environment is comfortable. Discuss the following issues:

- Review the nature and purpose of the research.
- No right or wrong answers, aim to understand experiences.
- Confidentiality, use of data.
- Explain the use of data recorder, transcription, use of pseudonym (invite to choose), use of verbatim quotes, will be taking field notes.
- Researcher aware that discussion might bring up difficult memories, explain can decline to answer any question or prompt; can ask to stop at any time if feels need to.
- Expected duration of interview.
- Check consent form sign and complete demographics questionnaire.
- Ask if any questions.

Check recorder working

Introduce and switch on tape recorder

General prompts

- Allow participant to respond uninterrupted and use open prompts if required to explore aspects of their experiences in depth.
- Can you tell me more about XXX?', 'What makes you say XXX? How did XX make you feel?

2. **Opening questions:**

Can you tell me about your experiences in providing care to women and families whose baby has died shortly before or during childbirth?

- *Allow participant to describe their role and experiences including personal experiences if appropriate.*
- *Can you tell me about the preparation you have received for your role in caring for parents whose baby has died (before the research)?*
- *Use prompts, as above to clarify aspects participants of experiences during pre- service education, continuing education and practice.*

3. **Experience of the research/intervention**

Can you describe your role in this research?

- *Explore specific activities, e.g. part of perinatal bereavement care group, activities as bereavement champion*

Why did you decide to be involved in the research?

What preparation and training did you have for your role in the research?

- *Explore perceptions of training.*

What effect do you think that the intervention/research has had on care provision for women and families after stillbirth or neonatal death?

4. **Development of services**

Is there anything else that could change, that would help you ensure quality of care for women and families whose baby has died around childbirth?

- *Explore: Service organisation factors, staffing environment, equipment, Individual factors; education, mentorship/ role modelling, perceptions/behaviours of the wider community*

5. **This research**

How do you feel about participating in this research?

How do you feel about participating in this interview?

Is there anything else you would like to add?

At the close of the interview briefly summarise the main points to confirm interpretation with the participant. Ask if they wish to expand any responses or add anything else to the discussion. Thank the participants for their time.

Ask how they feel after talking about these experiences, do they want you to contact anyone? Family, friend, colleague?

Ensure participant has contact details for research team should they wish to discuss any aspect of the study. Complete reflexive diary/field notes

Advancing care and support for women and families after stillbirth or neonatal death in Sub-Saharan Africa: A feasibility study

Interview Topic Guide

(Version 1.1, 24/07/19: Partners)

Interviews with women to explore experiences of care and support after stillbirth or neonatal death and the study intervention in Kenya and Uganda Interviews with

1. , setting ground rules:

Introduce self, thank participant for taking part and confirm agrees to interview taking place. Ensure environment is comfortable. Discuss the following issues:

- Review the nature and purpose of the research.
- No right or wrong answers, aim to understand experiences.
- Confidentiality, use of data.
- Explain the use of data recorder, transcription, use of pseudonym (invite to choose), use of verbatim quotes, will be taking field notes.
- Researcher aware that discussion might bring up difficult memories, explain can decline to answer any question or prompt; can ask to stop at any time if feels need to.
- Expected duration of interview.
- Check consent form signed, complete complete case report form and psychological questionnaire.
- Ask if any questions.

Check recorder working

Introduce and switch on tape recorder

General prompts

- Allow participant to respond uninterrupted and use open prompts if required to explore aspects of their experiences in depth.
- Can you tell me more about XXX?', 'What makes you say XXX? How did XX make you feel?

6. **Opening questions:**

   Can you tell a little about your partner's pregnancy, the birth and the death of your baby?

   - Establish the sex of the baby and use daughter or son in discussion. Follow their lead if unsure.
   - Allow participant to describe what happened, when and how

7. ***Care in facilities:***

   Can you tell us about the care your partner received whilst they were in the hospital/facility after the birth?

   - *Explore how they were told about the death, other communication with staff in facilities.*
   - *Did they visit the facility, how was this experience?*
   - *Did they or the partner see/hold they baby, how was this managed?*
   - *Explore length of stay in facility, discharge process.*
   - *Explore awareness of the intervention e.g. bereavement champions, any specific aspects of care which were helpful.*

8. ***Going home:***

   Can you tell me about your feelings, how you and your partner are coping since she came home from the facility?

   How did others respond to you following the death of your baby?

   - *Explore – experiences with family, friends?*

   Have you or your partner had any contacts with health workers since she came home?

   - *Any routine follow-up, explore advice and support*
   - *Explore any health problems for partner after the birth, access to care, how health issues impacted on coping with the death of the baby.*

   Explore awareness/access/uptake of the peer support component of the intervention?

   - *If they are aware that their partner accessed this, explore experiences.*
   - *Explore potential barriers to uptake (lack of access to phone, costs of calls, texts etc)*

9. ***Present situation:***

   Has anything in particular helped you cope with your baby's death?

   - *Explore cultural, religious beliefs and traditions.*

- *Explore any other sources of support.*

What could have improved your and your partner's experiences?

- *Explore any factors identified, including aspects of care or support in facilities or after discharge, including the intervention that might be altered or improved.*

10. ***This research:***

How do you feel about participating in this research?

How do you feel about participating in this interview?

Is there anything else you might want to add?

At the close of the interview briefly summarise the main points to confirm interpretation with the participant. Ask if they wish to expand any responses or add anything else to the discussion. Thank the participants for their time, offer $ 10USD KES/Uganda equivalent.

Ask how they feel after talking about these experiences, do they want you to contact anyone? Family, friend, health worker?

Ensure participant has contact details for the local research team should they wish to discuss any aspect of the study.
Complete reflexive diary/field notes.
.

Advancing care and support for women and families after stillbirth or neonatal death in Sub-Saharan Africa: A feasibility study

Interview Topic Guide

(Version 1, 22/05/19: Peer supporters delivering the intervention)

Interviews with health workers explore experiences of care and support after stillbirth or neonatal death and delivery of the intervention in Kenya and Uganda:

6. Introduction, setting ground rules:

Introduce self, thank participant for taking part and confirm agrees to interview taking place. Ensure environment is comfortable. Discuss the following issues:

- Review the nature and purpose of the research.
- No right or wrong answers, aim to understand experiences.
- Confidentiality, use of data.
- Explain the use of data recorder, transcription, use of pseudonym (invite to choose), use of verbatim quotes, will be taking field notes.
- Researcher aware that discussion might bring up difficult memories, explain can decline to answer any question or prompt; can ask to stop at any time if feels need to.
- Expected duration of interview.
- Check consent form sign and complete demographics questionnaire.
- Ask if any questions.

Check recorder working

Introduce and switch on tape recorder

General prompts

- Allow participant to respond uninterrupted and use open prompts if required to explore aspects of their experiences in depth.
- Can you tell me more about XXX?', 'What makes you say XXX? How did XX make you feel?

7. **Opening questions:**

Can you tell me about your own experiences of the death of your baby?

- *Establish the sex of the baby and use daughter or son in discussion. Follow their lead if unsure.*
- *Allow participant to describe what happened, when and how*

Did anything in particular help you cope with your baby's death?

- *Explore cultural, religious beliefs and traditions.*
- *Explore any other sources of support.*

What could have improved your experience?

- *Explore any factors identified by the woman, including aspects of care or support in facilities or after discharge, including the intervention that might be altered or improved.*

8. Experience of the research/intervention

Can you describe your role in this research?

- *Explore their perception of peer support, the specific activities they have undertaken, and experiences of contacts with women.*

Why did you decide to be involved in the research?

What preparation and training did you have for your role in the research?

- *Explore perceptions of training provided, did it prepare them adequately.*

What support was available to help you with your role as a peer supporter?

- *Explore contacts with bereavement care champions, the research team and any specific issues encountered*

What effect do you think that the intervention/research has had on care provision for women and families after stillbirth or neonatal death?

9. Development of services

Is there anything else that could change, that would help you ensure quality of care for women and families whose baby has died around childbirth?

- *Explore: Health services, care in facilities; education, mentorship/ role modelling, perceptions/behaviours of the wider community*

10. This research

How do you feel about participating in this research?

How do you feel about participating in this interview?

Is there anything else you would like to add?

At the close of the interview briefly summarise the main points to confirm interpretation with the participant. Ask if they wish to expand any responses or add anything else to the discussion. Thank the participants for their time.

Ask how they feel after talking about these experiences, do they want you to contact anyone? Family, friend, colleague?

Ensure participant has contact details for research team should they wish to discuss any aspect of the study.

Complete reflexive diary/field notes.

Advancing care and support for women and families after stillbirth or neonatal death in Sub-Saharan Africa: A feasibility study

Interview Topic Guide

(Version 1.1, 24/07/19: Women)

Interviews with women to explore experiences of care and support after stillbirth or neonatal death and the study intervention in Kenya and Uganda:

Introduction, setting ground rules:

Introduce self, thank participant for taking part and confirm agrees to interview taking place.

Ensure environment is comfortable. Discuss the following issues:

- Review the nature and purpose of the research.
- No right or wrong answers, aim to understand experiences.
- Confidentiality, use of data.
- Explain the use of data recorder, transcription, use of pseudonym (invite to choose), use of verbatim quotes, will be taking field notes.
- Researcher aware that discussion might bring up difficult memories, explain can decline to answer any question or prompt; can ask to stop at any time if feels need to.
- Expected duration of interview.
- Check consent form signed, complete case report form and psychological questionnaire.
- Ask if any questions.

Check recorder working

Introduce and switch on tape recorder

General prompts

- *Allow participant to respond uninterrupted and use open prompts if required to explore aspects of their experiences in depth.*
- *Can you tell me more about XXX?', 'What makes you say XXX? How did XX make you feel?*

1. **Opening questions:**

   Can you tell me about, your pregnancy, the birth and the death of your baby?

- Establish the sex of the baby and use daughter or son in discussion. Follow their lead if unsure.
- Allow participant to describe what happened, when and how

2. ***Care in facilities:***

   Can you tell us about the care you received whilst you were in the hospital/facility after the birth?

   - *Explore how they were told about the death, other communication with staff in facilities.*
   - *Did they see/hold they baby, how was this managed?*
   - *Explore length of stay in facility, discharge process.*
   - *Explore awareness of the intervention e.g. bereavement champions, any specific aspects of care which were helpful.*

3. ***Going home:***

   Can you tell me about your feelings and how you are coping since you came home?

   How did others respond to you following the death of your baby?

   - *Explore – experiences with partner, family and, friends?*

   Have you had any contacts with health workers since you came home?

   - *Any routine follow-up, explore advice and support*
   - *Explore any health problems after the birth, access to care, how health issues impacted on coping with the death of the baby.*

   Explore awareness/access/uptake of the peer support component?

   - *If they accessed this explore experiences.*
   - *Explore potential barriers to uptake (lack of access to phone, costs of calls, texts etc)*

4. ***Present situation:***

   Has anything in particular helped you cope with your baby's death?

   - *Explore cultural, religious beliefs and traditions.*
   - *Explore any other sources of support.*

   What could have improved your experience?

   - *Explore any factors identified by the woman, including aspects of care or support in facilities or after discharge, including the intervention that might be altered or improved.*

5. ***This research:***

   How do you feel about participating in this research?

   How do you feel about participating in this interview?

   Is there anything else you might want to add?

At the close of the interview briefly summarise the main points to confirm interpretation with the participant. Ask if they wish to expand any responses or add anything else to the discussion. Thank the participants for their time, offer $10 USD KES/Uganda equivalent.

Ask how they feel after talking about these experiences, do they want you to contact anyone? Family, friend, health worker?

Ensure participant has contact details for the local research team should they wish to discuss any aspect of the study.
Complete reflexive diary/field notes.

Appendix 10: Translated Topic Guides

Okutumbula endabilira n'obuyambi obuweebwa abakyaala n'abomu maka gaabwe oluvannyuma lwo'kufiirwa omwana mu lubuto oba mu mweezi gumu nga yaakazaalibwa mu kitundi kya Afirika ekiri wansi w'eddungu Sahara: Okunoonyereza okukakasa oba kisoboka.

Olupapula lw'ebibuuzo

(Version 1, 22/05/19: Ab'omu maka)

Ebibuuzo eri abakyala okumanya endabilira n'obuyambi bwe baweebwa oluvannyuma lwo'kufiirwa omwana mu lubuto oba mu mweezi gumu nga yaakazaalibwa n'enkola ez'okukozesebwa mu kunonyereza e'kenya n'eUganda

1. **Enyanjula, okuteekawo amateeka ag'okugobelera mu Kiseera eky'okubuuzibwa ebibuuzo.**

Weyanjule, webaze eyetabye mu kunonyereza era kakas anti akkirizza okwenyigira mu kunonyereza. Kakasa nti wemusisinkanye walungi. Mwoogerezeganye ku nsonga zino wammanga:

- Yita mukikula n'omugaso gw'okunonyereza
- Teli kyakuddamu kituufu oba kikyamu, gendelera okutegeera byeyayitamu
- Okukuuma ebi mwoogerako nga byakyaama, n'enkozesa y'ebivudde mu kunonyereza.

- Nyonyola omugaso gw'akuuma akakwata amaloboozi, okukyusa obubaka mu maloboozi okubiteeka mu buwandiike, okukozesa erinya eritali lilye (musabe yenonyeze), okukozesa byayogedde nga bwebiri, n'okuwandiika eby'ogeddwako.
- Omunonyereza amanyi nti okuwayaamu kuno kuyinza okuleetawo ebijjukizo aby'ennaku, nyonyola nti ayinza obutaddamu bibuuzo ebimu; asobola okukuyimiriza bwabanga awulira nti kyeetagisa.
- Obudde okubuuzibwa ebibuuzo kweebusuubira okutwaala.
- Kakasa nti olupapula olwokukiriza luliko omukono, maliriza okujjuza olupapula oluliko ebibuuzo, n'eliwandiiko ekikebera engeri gy'awuliramu mu mbeera ye ey'obwongo
- Mubuuze oba alina ekibuuzo kyonna

Kebera olabe oba akuuma akamaloboozi kakola bulungi

Weyanjule oteekeko akumma ak'amaloboozi.

Ebiyamba mu kubuuza

- Leka oyo eyeetabye mu musomo akuddemu nga tayimiriziddwa atte okozesa ebibuuzo ebyeyabiza bwekiba kyeetagisa okusobola okumanya byeyitamu mu bungi bwaabyo.
- Osobola okumbulira ekisingawo ku xxx?', 'kiki ekikureetera okugamba bwooti xxx?' kino xxx kikuyisizza kitya?'

2. Ebibuuzo ebitandika:

Kyandibadde kiliungi singa otandika n'okumbuulirako ku bikwatagana n'owomumaka go, abaana be, ne biki by'omanyi ku mwana ono eyafa?

Baleke banyonyole ekyaabawo, ddi lwekyaabawo ne wa wekyaabawo, nga tebataataganyizibbwa.

- *Zuula oluganda lw'alina ku mukyaala*
- Mubuuze obutonde bw'omwana era okozese "muwala" oba "mutabani" mu kiseera eky'okuwayaamu. Gobelera by'akugamba bw'oba tewekakasa

- Kkiriza eyetabye mu kunonyereeza anyonyole ekyaabawo, eddi era ne butya bwekyaabawo.

3. ***Obujanjabi mu malwaliro***

   Osobola okutubulira ebikwatagana ku bujanjabi ow'omumakago bwe yafuna mu dwaliro nga amaze okuzala?

   - *Zuula oba amanyi engeri gye bamubuliramu ku by'okufa kw'omwana, n'engeri endala gye yayogeramu n'abasawo b'omu malwaliro*
   - *Oba omukyala/omwami we yalaba/yasitulako ku mwaana, kino kyakolebwa kitya?*
   - *Zuula ebbanga lye baamala mu ddwaliro, n'engeri gyeyasiibulwa okuva mu ddwaliro.*
   - *Zuula kiki ky'amanyi ku bigenda okugezesebwa mu kunonyereza gamba nga: abasawo abatendeke mu kubudaabuda abazadde abafiiriddwa abaana, n'ebirala ebikwatagana ku ndabilira gyeyafuna nga byamuyamba.*

   - *Baagendako mu ddwaliro, yayisibwa atya bweyagendayo?*

4. ***Okuda ewaka***

   Osobola okumbulira omuntu w'omuka go engeri gy'abadde yewuliramu n'engeri gyeyayita mu mbeera eyokufiirwa omwaana okuva lwe yakomawo ewaka? Wewulira otya?

   Abalala bayogeraki ku w'omumaka go ono nga omwaana we amaze okufa (baamuyisa batya)?

   - *Buuza - byebayitamu n'omwami we/taata w'omwaana, ab'ewaka, n'emikwano?*

Omuntu w'omumaka go yali ayogeddeko n'abasawo (afunye obubaka bwonna okuva mu baswo) okuva lwe mwakomawo ewaka?

- *Enteekateeka zonna ez'okwongera okukubudaabuda, okuweebwa amagezi n'obuyambi obw'enjawulo. Okugoberera kwona nobubaka oba obuyambi*
- *Zuula ebizibu byonna omukyala byeyafuna mu bulamu bwe oluvannyuma lw'okuzaala, obusobozi bwaabwe okufuna obujjanjabi, nabutya ebizibu bino gyebikossessaamu engeri gyeyayita mu mbeera y'okifiirwa omwana.*

Zuula okumanya kwe/obusobozi bw'okufuna/n'enkozesa y'obuyambi bweyafuna okuva eri abakyaala b'okukyaalo abayambako okubudaabuda bannaabwe abafiiriddwa abaana

- *Bwaba nga akimanyi nti mukyaala we yafunye okubudabudibwa kuno, zuula butya bweyayisibwaamu*
- *Zuula ensonga ezisibola okuba nga zamulemesa okufuna obuyambi buno (obutabeera na ssimu, ssente z'okukuba esimu, ez'okuwereza obubaka ku ssimu, nebirala)*

5. Embeera eliwo kati:

Waliwo kyomanyi ekyayamba omuntu w'omu makago okuyita mu mbeera y'okufiirwa omwaana we?

- *Zuula enzikiriza ez'eby'obuwangwa, e'byeddiini n'ennono.*
- *Zuula wa obuyambi obulala gyebwaava*

Kiki kyolowooza ekyandimuyambye okuyita mu mbeera eyo?

- *Zuula ensonga ezizuuliddwa, nga kw'otadde n'endabilira/obuyambi bwebaafuna mu malwaliro oba nga bamaze okusiibulwa, nga kw'otadde n'edowooza ye ku biki ebiyinza okukyuusibwa/okwongerwamu omutindo mu nkola ezigezesebwa mu kunonyereza kuno. otaddamu nendabirila nokuyambibwa mudwaliro nga bamazze okusibula, ngo'taddeko nebikolebwa ebiyinza okukyusibwa oba okutumbuzibwa*
- ***Okunonyereza kuno:***

Wewulira otya oluvannyuma lw'okwenyigira mu musomo guno?

Wewulidde otya oluvanyuma lw'okubuuzibwa ebibuuzo bino?

Waliwo ekirala kyewandiyagadde okwongerako?

6. *Oluvanyuma lw'ebibuuzo wandiika mu bufunze ebintu ebivudde mu kunonyereza okusobola okukakasa engeri gy'otegedde mu ebubaka omuntu bwaakuwadde. Mubuuze oba yandiyagadde okwongerako ku byeboogedde oba ku byemuwayizzamu. Mweebaze olw'obudde bwaakuwadde era omuwe emitwaalo essatu (30,000=) egya Uganda.*

Mubuuze engeri gy'awuliramu oluvannyuma lw'okwoogera ku biki byeyitamu, oba yeetaga okwoogerko ne mukwano gwe oba omusawo yenna.

Kakasa anti omuntu eyenyigidde mu kunonyereza alina ebikwata ku banonyereza singa aba nga ayagadde okwogera ku kintu kyona ekikwata ku musomo guno.
Maliriza obutabo obw'okufumintiriza ku by'ogeddwaako/ebiwandiikiddwa ng'oli mu kifo ky'obadde mu.

Okutumbula endabilira n'obuyambi obuweebwa abakyaala n'abomu maka gaabwe oluvannyuma lwo'kufiirwa omwana mu lubuto oba mu mweezi gumu nga yaakazaalibwa mu kitundi kya Afirika ekiri wansi w'eddungu Sahara: Okunoonyereza okukakasa oba kisoboka.

Olupapula lw'ebibuuzo

(Version 1.1, 24/07/19: Abakyala)

Ebibuuzo eri abakyala okumanya endabilira n'obuyambi bwe baweebwa oluvannyuma lwo'kufiirwa omwana mu lubuto oba mu mweezi gumu nga yaakazaalibwa n'enkola ez'okukozesebwa mu kunonyereza e'kenya n'eUganda

1. Enyanjula, okuteekawo amateeka ag'okugobelera mu Kiseera eky'okubuuzibwa ebibuuzo

Weyanjule, webaze eyetabye mu kunonyereza era kakas anti akkirizza okwenyigira mu kunonyereza. Kakasa nti wemusisinkanye walungi. Mwoogerezeganye ku nsonga zino wammanga:

- Yita mukikula n'omugaso gw'okunonyereza
- Teli kyakuddamu kituufu oba kikyamu, gendelera okutegeera byeyayitamu
- Okukuuma ebi mwoogerako nga byakyaama, n'enkozesa y'ebivudde mu kunonyereza.
- Nyonyola omugaso gw'akuuma akakwata amaloboozi, okukyusa obubaka mu maloboozi okubiteeka mu buwandiike, okukozesa erinya eritali lilye (musabe yenonyeze), okukozesa byayogedde nga bwebiri, n'okuwandiika eby'ogeddwako.

- Omunonyereza amanyi nti okuwayaamu kuno kuyinza okuleetawo ebijjukizo aby'ennaku, nyonyola nti ayinza obutaddamu bibuuzo ebimu; asobola okukuyimiriza bwabanga awulira nti kyeetagisa.
- Obudde okubuuzibwa ebibuuzo kweebusuubira okutwaala.
- Laba nti olupapula olwokukiriza luliko omukono, maliriza okujjuza olupapula oluliko ebibuuzo, n'eliwandiiko ekikebera engeri gy'awuliramu mu mbeera ye ey'obwongo
- Mubuuze oba alina ekibuuzo kyonna

Kebera olabe oba akuuma akamaloboozi kakola bulungi

Weyanjule oteekeko akumma ak'amaloboozi.

Ebiyamba mu kubuuza

- Leka oyo eyeetabye mu musomo akuddemu nga tayimiriziddwa atte okozesa ebibuuzo ebyeyabiza bwekiba kyeetagisa okusobola okumanya byeyitamu mu bungi bwaabyo.

- Osobola okumbulira ekisingawo ku xxx?', 'kiki ekikureetera okugamba bwooti xxx?' kino xxx kikuyisizza kitya?'

1. **Ebibuuzo ebitandika:**

   Osobola okumbulirako ku bikwatagana n'olubuto bwe lwaali, engeri omwana gyeyazaalibwamu n'ngeri gyeyafaamu?

   - Manya obutonde bw'omwaana era okozese muwala oba mutabani mu kiseera eky'okuwayaamu. Gobelera by'akugamba bw'oba tewekakasa
   - Kkiriza eyetabye mu kunonyereeza anyonyole ekyaabawo, eddi era ne butya bwekyaabawo.

2. ***Obujanjabi mu malwaliro***

   Osobola okumbuulirako ebikwata ku bujanjabi bwewafuna mu dwaliro nga omaze okuzala?

   - *Zuula engeri gye bamubuliramu ku by'okufa kw/omwana, n'engeri endala gye yayogeramu n'abakozi b'omu malwaliro*
     - *Yagendako mu ddwaliro, yayisibwa atya bweyagenda yo?*

- *Oba yalaba/yasitulako ku mwaana, kino kyakolebwa kitya?*
- *Zuula ebbanga lye yamala mu ddwaliro, n'engeri gyeyasiibulwa okuva mu ddwaliro.*
- *Zuula kiki ky'amanyi ku bigenda okugezesebwa mu kunonyereza gamba nga: abasawo abatendeke mu kubudaabuda abazadde abafiiriddwa abaana, n'ebirala ebikwatagana ku ndabilira gyeyafuna nga byamuyamba.*

3. ***Okudda ewaka***

   Osobola okumbulira engeeri gye'wewuliramu, ne'ngeri gyoyise mumbeera eyo nga akomyeewo ewaka?

   Abalala baayogerera ki nga omaze okufiirwa omwaana wo (Baakuyisa batya)?

   - *Zuula engeri omwaami we, ab'omu maka n'emikwano gyebamuyisaami*

   Wayogeddeko n'abasawo okuva lwe wakomawo ewaka?

   - *Enteekateeka zonna ez'okwongera okukubudaabuda, okuweebwa amagezi n'obuyambi obw'enjawulo. Okugoberera kwona nobubaka oba obuyambi*
   - *Zuula ebizibu byonna omukyala byeyafuna mu bulamu bwe oluvannyuma lw'okuzaala, obusobozi bwaabwe okufuna obujjanjabi, nabutya ebizibu bino gyebikossessaamu engeri gyeyayita mu mbeera y'okifiirwa omwana.*
   - *Zuula ebizibu byona oluvanyuma lyokuzaala, okufuna obujanjabi, okukosebwa mubulamu kwakotaganya kutya kukugumira okufa kwomwaana*

Zuula okumanya kwe/obusobozi bw'okufuna/n'enkozesa y'obuyambi bweyafuna okuva eri abakyaala b'okukyaalo abayambako okubudaabuda bannaabwe abafiiriddwa abaana

- *Bwaba nga yafuna okubudabudibwa kuno, zuula butya bweyayisibwaamu*

- *Zuula ensonga ezisibola okuba nga zamulemesa okufuna obuyambi buno (obutabeera na ssimu, ssente z'okukuba esimu, ez'okuwereza obubaka ku ssimu, nebirala)*

4. ***Embeera yakakano:***

   Waliwo ekintu kyonna ekikuyambye okuyita mu mbeera ey'okufiirwa omwana wo?

   - *Zuula enzikiriza ez'eby'obuwangwa, e'byeddiini n'ennono.*
   - *Zuula wa obuyambi obulala gyebwaava*

   Kiki ky'olowooza ekyandiyambye gwe ne mukyalawo okuyita mu mbeera eno?

   - *Zuula ensonga ezizuuliddwa, nga kw'otadde n'endabilira/obuyambi bwebaafuna mu malwaliro oba nga bamaze okusiibulwa, nga kw'otadde n'edowooza ye ku biki ebiyinza okukyuusibwa/okwongerwamu omutindo mu nkola ezigezesebwa mu kunonyereza kuno. otaddamu nendabirila nokuyambibwa mudwaliro nga bamazze okusibula, ngo'taddeko nebikolebwa ebiyinza okukyusibwa oba okutumbuzibwa*

5. ***Okunonyereza kuno:***

   Wewulira otya oluvannyuma lw'okwenyigira mu musomo guno?

   Wewulidde otya oluvanyuma lw'okubuuzibwa ebibuuzo bino?

   Waliwo ekirala kyewandiyagadde okwongerako?

Oluvanyuma lw'ebibuuzo wandiika mu bufunze ebintu ebivudde mu kunonyereza okusobola okukakasa engeri gy'otegedde mu ebubaka omuntu bwaakuwadde. Mubuuze oba yandiyagadde okwongerako ku byeboogedde oba ku byemuwayizzamu. Mweebaze olw'obudde bwaakuwadde era omuwe emitwaalo essatu (30,000=) egya Uganda. Mubuuze engeri gy'awuliramu oluvannyuma lw'okwoogera ku biki byeyitamu, oba yeetaga okwoogerko ne mukwano gwe oba omusawo yenna.

Kakasa anti omuntu eyenyigidde mu kunonyereza alina ebikwata ku banonyereza singa aba nga ayagadde okwogera ku kintu kyona ekikwata ku musomo guno.
Maliriza obutabo obw'okufumintiriza ku by'ogeddwaako/ebiwandiikiddwa ng'oli mu kifo ky'obadde mu.

Okutumbula endabilira n'obuyambi obuweebwa abakyaala n'abomu maka gaabwe oluvannyuma lwo'kufiirwa omwana mu lubuto oba mu mweezi gumu nga yaakazaalibwa mu kitundi kya Afirika ekiri wansi w'eddungu Sahara: Okunoonyereza okukakasa oba kisoboka.

Olupapula lwebibuuzo

(Version 1.1, 24/07/19: Abaami)

Ebibuuzo eri abakyala okumanya endabilira n'obuyambi bwe baweebwa oluvannyuma lwo'kufiirwa omwana mu lubuto oba mu mweezi gumu nga yaakazaalibwa n'enkola ez'okukozesebwa mu kunonyereza e'kenya n'eUganda

1. Enyanjula, okuteekawo amateeka ag'okugobelera mu Kiseera eky'okubuuzibwa ebibuuzo

Weyanjule, webaze eyetabye mu kunonyereza era kakas anti akkirizza okwenyigira mu kunonyereza. Kakasa nti wemusisinkanye walungi. Mwoogerezeganye ku nsonga zino wammanga:

- Yita mukikula n'omugaso gw'okunonyereza
- Teli kyakuddamu kituufu oba kikyamu, gendelera okutegeera byeyayitamu
- Okukuuma ebi mwoogerako nga byakyaama, n'enkozesa y'ebivudde mu kunonyereza.

- Nyonyola omugaso gw'akuuma akakwata amaloboozi, okukyusa obubaka mu maloboozi okubiteeka mu buwandiike, okukozesa erinya eritali lilye (musabe yenonyeze), okukozesa byayogedde nga bwebiri, n'okuwandiika eby'ogeddwako.
- Omunonyereza amanyi nti okuwayaamu kuno kuyinza okuleetawo ebijjukizo aby'ennaku, nyonyola nti ayinza obutaddamu bibuuzo ebimu; asobola okukuyimiriza bwabanga awulira nti kyeetagisa.
- Obudde okubuuzibwa ebibuuzo kweebusuubira okutwaala.
- Laba nti olupapula olwokukiriza luliko omukono, maliriza okujjuza olupapula oluliko ebibuuzo, n'eliwandiiko ekikebera engeri gy'awuliramu mu mbeera ye ey'obwongo
- Mubuuze oba alina ekibuuzo kyonna

Kebera olabe oba akuuma akamaloboozi kakola bulungi

Weyanjule oteekeko akumma ak'amaloboozi.

Ebiyamba mu kubuuza

- Leka oyo eyeetabye mu musomo akuddemu nga tayimiriziddwa atte okozesa ebibuuzo ebyeyabiza bwekiba kyeetagisa okusobola okumanya byeyitamu mu bungi bwaabyo.

- Osobola okumbulira ekisingawo ku xxx?', 'kiki ekikureetera okugamba bwooti xxx?' kino xxx kikuyisizza kitya?'

2. **Ebibuuzo ebitandika:**

Osobola okumbulirako ku bikwatagana n'olubuto lwa mukyaala wo, engeri omwana gyeyazaalibwamu n'ngeri gyeyafaamu?

- Manya obutonde bw'omwaana era okozese muwala oba mutabani mu kiseera eky'okuwayaamu. Gobelera by'akugamba bw'oba tewekakasa
- Kkiriza eyetabye mu kunonyereeza anyonyole ekyaabawo, eddi era ne butya bwekyaabawo.

3. Obujanjabi mu malwaliro

Osobola okutubulira ebikwatagana ku bujanjabi mukyala wo bwe yafuna mu dwaliro nga amaze okuzala?

- *Zuula engeri gye bamubuliramu ku by'okufa kw/omwana, n'engeri endala gye yayogeramu n'abakozi b'omu malwaliro*
  - *Baagendako mu ddwaliro, yayisibwa atya bweyagendayo?*
- *Oba mukyala we yalaba/yasitulako ku mwaana, kino kyakolebwa kitya?*
- *Zuula ebbanga lye baamala mu ddwaliro, n'engeri gyeyasiibulwa okuva mu ddwaliro.*
- *Zuula kiki ky'amanyi ku bigenda okugezesebwa mu kunonyereza gamba nga: abasawo abatendeke mu kubudaabuda abazadde abafiiriddwa abaana, n'ebirala ebikwatagana ku ndabilira gyeyafuna nga byamuyamba.*

4. Okuda ewaka:

Osobola okumbulira engeeri gye'wewuliramu, engeri gwe ne mukyalawo gye'muyise mu mbeera eno nga akomyeewo ewaka okuva mu ddwaliro?

Abalala bayogeraki ku kufa kwo'mwaana wo (Baakuyisa batya oluvannyuma lw'okufa kw'omwana?

- *Zuula engeri ab'omumaka n'emikwano gyebamuyisaamu*

Gwe ne'mukyala wo mwayogeddeko n'abasawo okuva lwe mwakomawo ewaka?

- *Enteekateeka zonna ez'okwongera okukubudaabuda, okuweebwa amagezi n'obuyambi obw'enjawulo. Okugoberera kwona nobubaka oba obuyambi*
- *Zuula ebizibu byonna omukyala byeyafuna mu bulamu bwe oluvannyuma lw'okuzaala, obusobozi bwaabwe okufuna obujjanjabi, nabutya ebizibu bino gyebikossessaamu engeri gyeyayita mu mbeera y'okifiirwa omwana.*

Zuula okumanya kwe/obusobozi bw'okufuna/n'enkozesa y'obuyambi bweyafuna okuva eri abakyaala b'okukyaalo abayambako okubudaabuda bannaabwe abafiiriddwa abaana

- *Bwaba nga akimanyi nti mukyaala we yafunye okubudabudibwa kuno, zuula butya bweyayisibwaamu*
- *Zuula ensonga ezisibola okuba nga zamulemesa okufuna obuyambi buno (obutabeera na ssimu, ssente z'okukuba esimu, ez'okuwereza obubaka ku ssimu, nebirala)*

5. ***Embeera eliwo kati:***

   Waliwo ekintu kyonna ekikuyambye okuyita mu mbeera ey'okufiirwa omwana wo?

   - *Zuula enzikiriza ez'eby'obuwangwa, e'byeddiini n'ennono.*
   - *Zuula wa obuyambi obulala gyebwaava*

   Kiki ky'olowooza ekyandiyambye gwe ne mukyalawo okuyita mu mbeera eno?

   - *Zuula ensonga ezizuuliddwa, nga kw'otadde n'endabilira/obuyambi bwebaafuna mu malwaliro oba nga bamaze okusiibulwa, nga kw'otadde n'edowooza ye ku biki ebiyinza okukyuusibwa/okwongerwamu omutindo mu nkola ezigezesebwa mu kunonyereza kuno. otaddamu nendabirila nokuyambibwa mudwaliro nga bamazze okusibula, ngo'taddeko nebikolebwa ebiyinza okukyusibwa oba okutumbuzibwa*

6. ***Okunonyereza kuno:***

   Wewulira otya oluvannyuma lw'okwenyigira mu musomo guno?

   Wewulidde otya oluvanyuma lw'okubuuzibwa ebibuuzo bino?

   Waliwo ekirala kyewandiyagadde okwongerako?

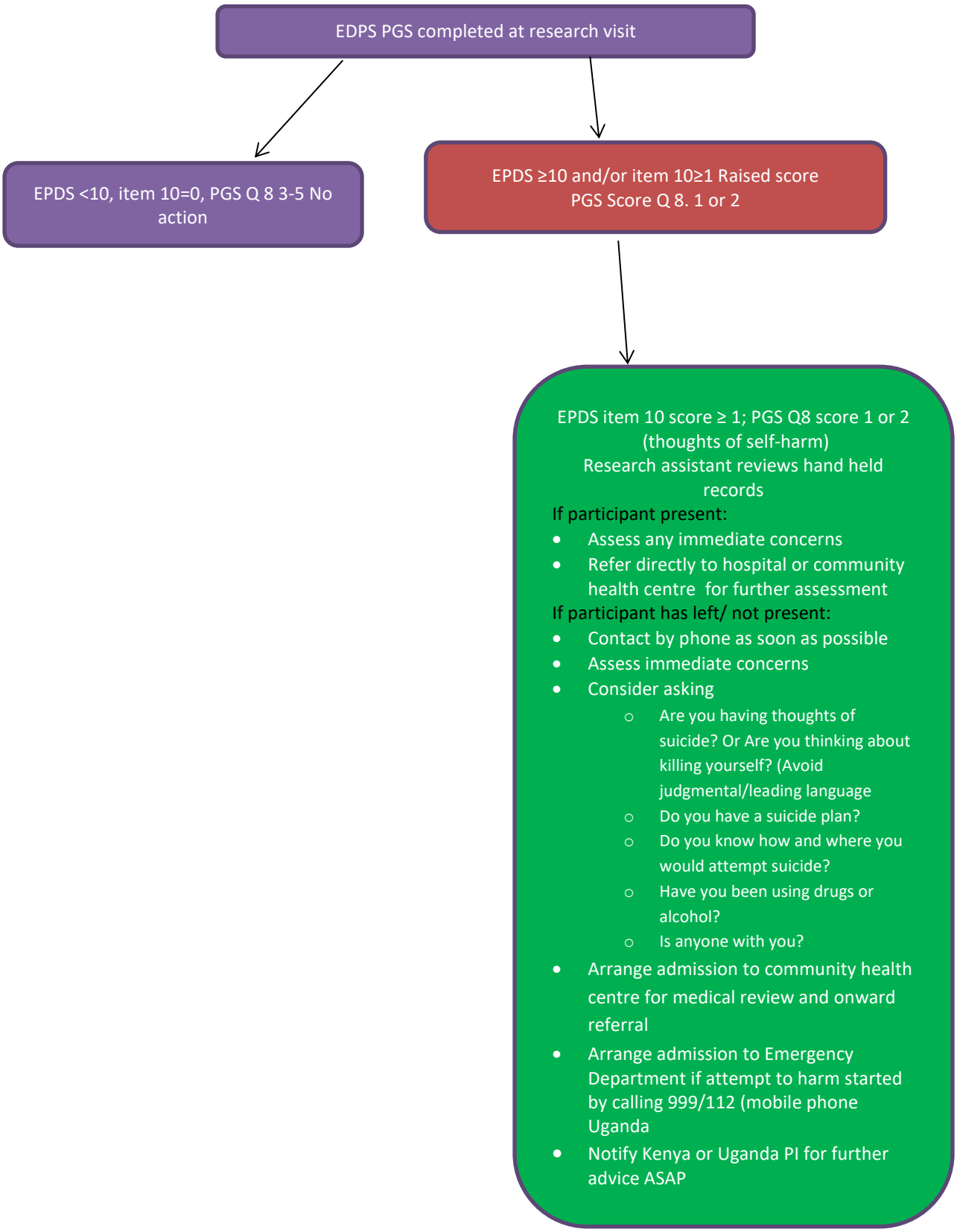
Oluvanyuma lw'ebibuuzo wandiika mu bufunze ebintu ebivudde mu kunonyereza okusobola okukakasa engeri gy'otegedde mu ebubaka omuntu bwaakuwadde. Mubuuze

oba yandiyagadde okwongerako ku byeboogedde oba ku byemuwayizzamu. Mweebaze olw'obudde bwaakuwadde era omuwe emitwaalo essatu (30,000=) egya Uganda. Mubuuze engeri gy'awuliramu oluvannyuma lw'okwoogera ku biki byeyitamu, oba yeetaga okwoogerko ne mukwano gwe oba omusawo yenna.

Kakasa anti omuntu eyenyigidde mu kunonyereza alina ebikwata ku banonyereza singa aba nga ayagadde okwogera ku kintu kyona ekikwata ku musomo guno.
Maliriza obutabo obw'okufumintiriza ku by'ogeddwaako/ebiwandiikiddwa ng'oli mu kifo ky'obadde mu.

Appendix 11: Response to raised EPDS scores

Response to raised EDPS scores and thoughts of self-harm (Postnatal Women) V1.1 24/07/19



Appendix 12: Lone worker Procedure

Advancing care and support for women and families after stillbirth or neonatal death in Sub-Saharan Africa: A feasibility study

Lone Working Procedure (Version 1: 22/05/19)

Data collection will involve episodes of lone working, to minimise the risk to researchers the principles of Division of Nursing, Midwifery and Social Work, Safety guidance for research fieldwork will be followed.

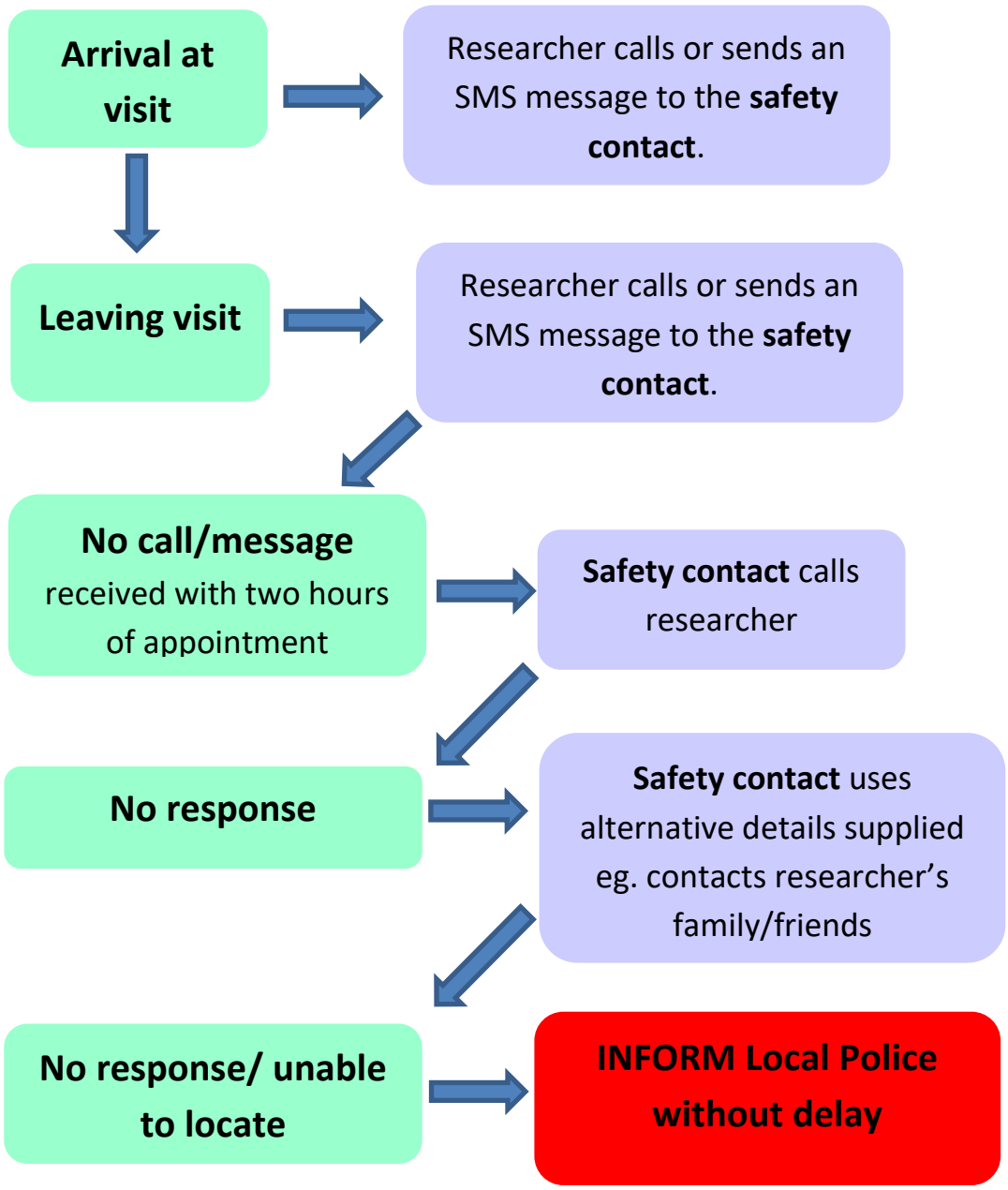
General

- Researchers will use office contact details on study materials and study specific mobile phones to avoid disclosing personal address/ telephone details.
- A local risk project assessment will be conducted prior to data collection commencing for the study.

Preparation for research visits

- An individual risk assessment will be conducted prior to each visit outside hospital or health centre.
- Visits will be scheduled during normal working hours whenever possible; visits to higher risk areas will not be made after dark.
- The researcher will confirm the time and date of the visit by phone/ or SMS and advise that they will carry identification.
- Appropriate travel arrangements will be made in advance and the researcher will carry a fully charged mobile phone.
- The schedule of fieldwork trips will be shared in writing with the local PI, who will normally act as **safety contact** during the visit. If the local PI is not available another member of academic/clinical or administrative staff will be designated to take on this role.
- The researcher will provide the safety contact with a Lone Working form in a sealed envelope which has personal details and details of the visit, including address listed on it.
- The following flow chart summarises actions which will be performed immediately before during, and after visits.

Lone Worker Procedure (from arrival at visit)



If an adverse incident or near miss occurs during data collection, an incident report will be compiled by the researcher submitted, to the local PI and Chief Investigator and escalated to the Divisional Research Committee if appropriate.

Appendix 13: MAK SHS-IRB Adverse event reporting form_104

MAKERERE UNIVERSITY

SCHOOL OF HEALTH SCIENCES

RESEARCH AND ETHICS COMMITTEE (MakSHS-REC)

COLLEGE OF HEALTH SCIENCES

REC FORM 104

ADVERSE EVENT REPORTING FORM

Complete entire form. Do not leave any blanks and the soft copy should be sent to this email address:**healthsciences.irb@gmail.com**

MakSHS-REC Protocol #:		**PI Institution :**	
Principal Investigator:		**Phone:** **Email:**	
Report prepared by:		**Phone:** **Email:**	
Study Title:			
Study Sponsor:			
Date of Adverse Event:	**Subject's Initials or Study #:**	**Type of Report:** ☐ Initial ☐ Follow-up	

Date when the study staff became aware of the event:		
Brief Description of Adverse Event (including diagnosis):		

Location of Adverse Event:

_____

Research involves a: ☐ Drug

☐ Device

☐ Procedure

_____

_____

Name of Drug, Device or Procedure:

Is the drug/device investigational: ☐ Yes

☐ No

Has the Adverse Event been reported to:

☐ Sponsor, Date of report

☐ REC, Date of report

Adverse Event appears to be (check one):

☐ Not related ☐ Unlikely ☐ Possibly related

☐ Probably related ☐ Related ☐ Unknown

Expectedness: ☐ Expected ☐ Not expected

Severity of Adverse Event:

☐ Mild ☐ Moderate ☐ Severe ☐ Fatal

Outcome of Adverse Event:

☐ Death (due to event) ☐ Death (due to other causes)

☐ Hospitalization ☐ Extended Hospitalization

☐ Congenital Abnormality ☐ Recovered

☐ Not yet recovered

Recovery of Subject:

☐ Complete ☐ Moderate ☐ Minimal

☐ None ☐ Not yet resolved ☐ Unknown

Was this Adverse Event addressed in the protocol and consent form?	☐ Yes ☐ No ☐ N/A
Was this Adverse Event addressed in Investigators Brochure?	☐ Yes ☐ No ☐ N/A
Are changes required to the protocol?	☐ Yes ☐ No ☐ N/A
Are changes required to the consent form?	☐ Yes ☐ No ☐ N/A
If changes are **required**, please attach a copy of the revised protocol/consent form *with changes highlighted with a bright coloured highlighter.*	
If changes are **not required**, please explain as to why changes to the protocol /consent form are not necessarily based on the event.	

From the data obtained or from currently available information, do you see any need to reassess the risks and benefits to the subjects in this research? ☐ Yes ☐ No

_____ _____

P.I. Signature Date

Note: Serious adverse events should be reported within 7 days while minor adverse events may be submitted in the annual report.

Appendix 14: Timelines (GANT Chart)

WS 3 Bereavement care intervention feasibility study : Study timeline												
Month/date	Aug '19 1	Sep 2	Oct 3	Nov 4	Dec 5	Jan 6	Feb 7	Ma 8	Apr 9	Ma 10	Jun 11	Jul '20 12
	Phase 1 (Pre implementation)						Phase 2 (Implementation)					
Research governance approvals												
Start-up meeting												
Development of training package												
Training for intervention												
Perinatal Bereavement care group meetings												
Recruitment (phase 1; control)												
Data collection (phase 1)												
Intervention introduced												
Recruitment (phase 2 women)												
Data collection (phase 2 women) Recruitment and data collection partners, health workers)												
Data analysis (both phases)												
Dissemination meeting												
Reporting												
Development of trial protocol												

Appendix 15: Study budget

No	Items	Amount
1.	Research equipment and maintenance	£ 150
2.	Ethics approvals	£ 500
3.	Research consumables/stationery	£500
4.	Travels and subsistence	£1000
5.	Data collection	£20,000
6.	Transcription and translation	£500
7.	Rep[ort and manuscript writing	£30,000
8.	Stakeholders' meetings	£1,680
9.	Conference fees	£500
	Total	**£54,830**

Appendix 16: Consent forms