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Better Maternity Care Pathways in Pregnancy after Stillbirth or Neonatal Death: A feasibility study

PROTOCOL
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Contents

1. RESEARCH TEAM & KEY CONTACTS

Chief Investigator:

Name: **Dr Tracey A Mills**

Address: Division of Nursing, Midwifery and Social Work, School of Health Sciences, Faculty of Biology, Medicine and Health, The University of Manchester
Room 4.334
Jean Mc Farlane Building
Oxford Rd
Manchester
M13 9PL

Email: tracey.mills@manchester.ac.uk

Telephone: 0161 306 7709

Co Investigators:

Professor Dame Tina Lavender, Professor of Midwifery, Division of Nursing, Midwifery and Social Work, The University of Manchester

Dr Alexander Heazell, Clinical Senior Lecturer in Obstetrics, The University of Manchester

Dr Steve Roberts, Senior Lecturer in Statistics, The University of Manchester

Dr Debbie Smith, Senior Lecturer in Psychology, Leeds Trinity University

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

Claire Storey, PPI Representative

Cathie Melvin, Research Midwife Co-ordinator, East Lancashire Hospitals NHS Trust

Karen Clough, Specialist Midwife, Pennine Acute Trust

Rachel Newport, Research Midwife, Pennine Acute Trust

Sponsor(s):	***Lead R&D Trust contact(s):***
Name: The University of Manchester Sponsor contact: Ms Lynne McRae Address: Faculty of Biology, Medicine and Health 1.21A Simon Building The University of Manchester Brunswick Street Manchester M13 9PL Email: lynne.macrae@manchester.ac.uk Telephone: 0161 275 5436	Name: Catherine Gedling R&D Manager Address : Research and Development Department East Lancashire Hospitals NHS Trust Royal Blackburn Hospital Haslingden Road Blackburn Lancs BB2 3HH Email: catherine.gedling@elht.nhs.uk Telephone: 01254 732115

2. INTRODUCTION

In the UK, 13 babies die shortly before or soon after birth every day, causing long lasting grief for parents. Most women who have had a stillbirth or neonatal death conceive again, often soon after the loss. Subsequent pregnancies are associated with high stress and anxiety for parents, increasing complications such as the baby being born too early or too small. Difficult feelings and emotions often persist, even after the birth of a healthy baby and can disrupt early bonding, making family and social problems more likely later in life. Sensitive and appropriate support is vital for parents in pregnancy after the death of a baby. However, our recent research demonstrated that not all parents had good care all of the time; tactless and insensitive communication and lack of emotional support were common issues.

This study will examine whether it is possible to conduct research testing a new package of care to improve support for parents who have previously experienced death of a baby. Women would have a named midwife care co-ordinator, who would deliver antenatal care alongside their doctor, maintain a relationship with the family in pregnancy and during the early days after birth and provide access to extra support. This change will be introduced with a small group of women in two hospitals in North-West England and compared with similar women who received care immediately prior to the change. 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 larger study to assess whether this change would benefit women, represents good value for money and should be introduced to the NHS.

3. BACKGROUND

Perinatal death is now recognised as precipitating prolonged grief, comparable to any child death (Barkway, 1997). After the death of their baby, most women conceive again, 50% within a year (Hughes et al., 1999). Subsequent pregnancies are associated with increased maternal anxiety and emotional vulnerability, particularly when the inter-pregnancy interval is short (Armstrong and Hutti, 1998; Hughes et al., 1999). This is a concern because of links with adverse outcomes, notably preterm birth and low birth weight (Mulder et al., 2002). Longer term negative psychological impacts, persisting

despite the birth of a healthy child increase the risks of disrupted maternal-infant attachment and parenting difficulties in affected families (Blackmore et al., 2011; O'Leary et al., 2011). Women who are pregnant after stillbirth or neonatal death are normally considered 'high-risk', receive obstetric-led care and give birth in a specialist maternity unit (Royal College of Obstetricians and Gynaecologists, 2010). Increased antenatal surveillance is justified by the increased risk of recurrence associated with previous late perinatal death (Getahun et al., 2009). Whilst the emotional and psychological consequences of perinatal bereavement and the importance of adequate emotional support in subsequent pregnancy are increasingly recognised, there is little practical guidance for professionals in planning care to most effectively meet parents' needs (Royal College of Obstetricians and Gynaecologists, 2010). Our recent qualitative metasynthesis of the literature surrounding maternity care in subsequent pregnancies confirmed profound effects of bereavement on parents' experiences (Mills et al., 2014). Parents consistently describe high stress, anxiety and doubt the likelihood of a positive outcome. These negative and fluctuating emotions often triggered tensions in close personal relationships related to perceived lack of understanding among family and friends of their inability to 'get over' the loss and 'move on' with the new baby(Cote-Arsenault and Donato, 2007). Isolation from conventional support networks increased parent's reliance on health professionals for emotional support during pregnancy. Two studies evaluated specialist targeted support programmes for parents in subsequent pregnancy in North America and Australia (Caelli et al., 2002; Cote-Arsenault and Freije, 2004). Both involved regular antenatal, labour and postnatal contacts with a hospital-based facilitator (nurse or midwife). Participants were also offered access a professional/peer-support group, the opportunity to build relationships with other bereaved parents was particularly highly valued, indicating benefits of group approaches for parents in subsequent pregnancy (Yalom and Leszcz, 2005).

The literature review exposed a dearth of UK-focused research, therefore we conducted a qualitative exploratory study of service provision and parents' experiences of care in the UK (Improving Support in Pregnancy following Stillbirth or Neonatal Death: Funder Tommy's). A national survey drew responses from 546 women, across all UK regions with experience of care in subsequent pregnancy and over 60% of NHS maternity units (Mills et al., 2016). In-depth qualitative interviews were also conducted with 13 women, 11 male partners and 12 health professionals from North-West England. Confirming and extending the metasynthesis, we demonstrated a lack of equity in current care provision within UK maternity services. Although some examples of excellent care were identified; negative experiences were also common. Recurrent themes included poor communication,

including tactless and insensitive comments from professionals who appeared to be unaware of parents' previous history. Some professionals displayed a lack of empathy, for example, several parents reported unwillingness to discuss the plan of care and mode of birth early in pregnancy, potentially compromising control and self-efficacy (Bandura, 1977).Whilst individual staff behaviours undoubtedly affected overall perceptions of care, aspects of organisation and delivery of services were also important. Lack of relational continuity was a consistent issue in poor experiences. Parents rarely saw the same professionals at their antenatal appointments; several women recalled severe distress at having to repeatedly recount details of their previous baby's death. This accumulating evidence questions the adequacy of current care, particularly in ensuring equity of access to appropriate and sensitive emotional support for this potentially vulnerable group of parents. Within the standard model of high-risk obstetric care, parents encounter multiple professionals during antenatal, intrapartum and postnatal contacts; Tracy et al. (2011) reported up to 20 different midwives over the course of a pregnancy. This approach has come under increasing scrutiny; fragmentation is associated with reduced maternal satisfaction and rising intervention in childbirth, particularly increased rates of Caesarean section (ten Hoope-Bender, 2013). The relationship between the mother(parents) and the midwife, who has the most direct and intimate contacts with the family is recognised as, perhaps, the most important influence on perceptions of emotional support and quality of care(Hunter, 2001),therefore the impact of improved continuity of midwifery care has been an important focus for research. Randomised controlled trials of midwife-led and case-holding models in low and high-risk pregnancies have demonstrated reduction in interventions, safety, cost effectiveness and improved maternal satisfaction compared to standard care (Sandall et al., 2013; Tracy et al., 2011; Tracy et al., 2013). However, continuity models have not been widely implemented within UK maternity care, even for 'low risk' women; a national survey of 23,000 women in 2013 reported that only 34% of women saw the same midwife for most or all antenatal visits (Care Quality Commission, 2014). The underlying reasons are poorly understood but concerns around sustainability may contribute; many midwives express negative perceptions of the introduction of caseload models which provide optimum continuity but demand increased flexibility and 24 hour on-call commitments (Sandall et al., 2015). Cultural clashes with established structures in maternity care may also act as a barrier (McLachlan et al., 2012).

In subsequent pregnancies parents, arguably, have a greater need for intensive midwifery support and providing increased continuity of care would plausibly address many of the shortcomings identified in existing services. However, research in this area is lacking. The Midwifery 2020 report (Chief Nursing Officers for England, 2010) identified the midwife as

'coordinator of care, for all women with complex pregnancies', emphasising the pivotal role for the known midwife 'in coordinating the journey through pregnancy ensuring that… holistic care is provided to optimise each woman's birth experience regardless of risk factors.' (pg. 23); but provided little guidance on how this would be facilitated in practice. More recently, the National Maternity Review has renewed impetus for more personalised, responsive care and including better midwifery continuity and increased the need for robust evidence to support development of midwifery practice in this area(National Maternity Review, 2016). The care co-ordinator model evolved in other healthcare settings, improving satisfaction with care and cost effectiveness for patients with long-term conditions (Nutt and Hungerford, 2010; Wise et al., 2007). This study would be the first to explore implementation of care co-ordination in UK maternity services for a vulnerable group with unmet needs.

4. STUDY OBJECTIVES

4.1. Primary Question/Objective:

To explore the feasibility of a trial of a multicomponent intervention focused on a midwife care co-ordinator to improve parents' experiences and psychological wellbeing in pregnancy after stillbirth.

4.2. Secondary Question/Objective:

- To assess the willingness of women and their partners (spouse or domestic partner) or birth partners (other person identified by the woman herself as providing the main source of support in pregnancy e.g. family member, friend) to participate in the research and continue in the study until completion.
- To explore the views and experiences of women and their partners of participation in the study and of the maternity care pathway for the intervention and control groups.
- To explore the views and experiences of maternity care professionals involved in delivery of the intervention on participation in the research and the impact of the new care package on wider service provision.

In preparation for a definitive trial, also:

- *Explore the assessment of psychological constructs which have been previously identified as impacting significantly on the wellbeing of parents and families in*

pregnancy after stillbirth or neonatal death, including anxiety, worry, stress, depression, maternal-infant attachment and self-efficacy.

- *Examine participants' experiences of completing questionnaires to ascertain the burden and acceptability of this element of the design*
- *Generate qualitative data to identify additional psychological outcomes and define those most important for parents.*
- *Define other appropriate clinical outcomes, including sample sizes required.*
- *Determine the feasibility of a full economic evaluation of the intervention, through exploration of the key cost elements and the most useful methodology to assess these including ascertaining acceptability/completion rates for the EQ-5D in this population.*
- *Explore methods of assessment of the fidelity of the intervention; to compare the delivery, uptake and experiences of components of the intervention in practice during the study to what was proposed in the protocol.*

5. STUDY DESIGN & PROTOCOL

Following the MRC framework for development and testing of complex interventions in healthcare (Craig et al., 2008), a prospective, mixed-methods study (Cresswell, 2003; Tashakkori and Teddlie, 2002) will be conducted using a pre- and post-observational cohort design, to allow assessment of important elements of the processes involved in a definitive trial.

5.1. Participants

5.1.1. Setting:

Two maternity units in North-West England: East Lancashire Healthcare Trust and Pennine Acute Trust. The proposed sites are large obstetric units with 6450 (East Lancs.) and 5219 (Royal Oldham, Pennine Acute Trust) births in 2014-15, respectively.

5.1.2. Sample:

Forty pregnant women (20 in each site) who have previously experienced a stillbirth or neonatal death, are ≤20 weeks pregnant and not eligible for a specialist maternity service (e.g: cardiac disease, diabetes) will be recruited to the intervention. A separate group of 20 women (10 in each site) meeting the same criteria, having the current pattern of care at the same units, in the six months immediately preceding the introduction of the intervention will be recruited as

controls to explore experiences of care and pilot data collection for a subsequent trial.

Across both clinical sites, up to 12 women participating in the control phase of the study, and up to 25 women will also be invited to be face to face or telephone interviews. Partners (or birth partners where they are the main source of support) of women participants will be recruited to explore experiences through questionnaires (partners only) and interviews (partners or birth partners; sub sample of up to 8 control phase, up to 12 intervention phase). Additionally health professionals involved in care (up to 15) will be recruited for interviews to explore their experiences of the research and the intervention.

A total of 60 pregnant women, up to 40 partners (estimate) and 15 health professionals will be recruited for the study.

5.2. Study Phases:

5.2.1. Control phase:

Participants recruited during the control phase (months 3-8) will have existing care provided for women after previous perinatal death in the unit. There is no current defined national pathway for care in pregnancy following stillbirth or neonatal death. The control phase of the study will provide clearer understanding of usual care in the participating sites. In the absence of a definitive non-recurring diagnosis (e.g. fetal abnormality recurrence excluded on ultrasound scan, women are classified as having a high risk pregnancy. Therefore, antenatal care will be consultant-led, antenatal visits will take place in the hospital, involving the members of the obstetric team and antenatal clinic midwives, but the woman will not necessarily be reviewed by the consultant in person at each visit. Additionally, some visits may also take place in the community clinics with the midwife. The actual pattern, location of visits and additional investigations will be determined on an individual basis depending on an assessment of the woman's needs, local service configuration and be influenced by individual clinician practice and preference. After the booking appointment, all multiparous women receive no less than 5 visits up to 38 weeks' gestation with an additional visit at 41 weeks to assess for induction of labour if still pregnant (NICE, 2008). Additional monitoring and investigations will be requested according to clinical need, following national guidance (Royal College of Obstetricians and Gynaecologists, 2010). The standard

antenatal education programme will be available. Intrapartum care will be provided in the obstetric unit and postnatal care by the community midwifery team, until transfer to primary care, up to 28 days after birth.

5.2.2. Intervention phase:

Women recruited from month 9-21 will be offered the study intervention in addition to usual care. This has been informed by our review and metasynthesis of the literature (Mills et al., 2014) and will include the following:

5.2.2.1. Care co-ordination

Women will be allocated a care co-ordinator; a registered midwife (hospital or community based), experienced in caring for previously bereaved parents with specific training in the intervention. The midwives undertaking this role at each site will be supported by at least one *'buddy'* midwife (arrangements negotiated locally), who has received the same training and will provide cover during annual leave or sickness/absence.

Table 1 outlines the activities of the care coordinator/buddy

Table 1: Care Co-ordination	
When	What
Recruitment	• Meet with parents • With lead obstetrician, devise/ review care plan to include schedule of visits, monitoring any additional investigation.
Antenatal contacts	• Provide midwifery care, where possible, during scheduled antenatal visits. • If woman having additional appointments/investigations e.g. medical clinics, liaise with multidisciplinary professionals, departments to ensure effective communication. • Provide a contact number/method for **non-urgent** use during contact hours, maintain regular contact (by woman's preferred method SMS, call, email, e.g. 1-2 weekly to ascertain need for further support).
Intrapartum care plan	• Initiate discussion/planning of intrapartum care, determine individual needs and preferences. Written plan in notes, visit labour ward, introductions to staff.
Postnatal	• Make contact within 72 hours of birth, final contact before transfer to (primary care) health visitor.

5.2.2.2. Additional support

During the intervention phase women will also have access to additional support:

A monthly support session will be held at each clinical site; women and partners will be invited from recruitment to the end of the postnatal period (transfer to primary care). Sessions will be facilitated by the research and clinical midwifery team. The content will be flexible and user-led, with the focus on peer support and opportunities for sharing experiences including:

- Targeted antenatal education based on the 'Preparation for Birth and Beyond' framework (Department of Health, 2011) utilising active and participatory learning and development of nonprofessional
- Peer and social networks (also a study WhatsApp social media group) to enhance long-term support.

Training will be provided for care co-ordinators and buddies in a 'Coping *strategy toolbag'* (Appendix 1) including simple psychological techniques that can be explained to women and partners during contacts. These are designed to enhance abilities to cope with fluctuating emotions including stress and anxiety during pregnancy/ postnatal period. The techniques will be based on health psychology theory and aim to increase parent's self-efficacy (Bandura, 1977).

6. STUDY PARTICIPANTS

6.1. Inclusion Criteria:

6.1.1. Women and Partners:

- Pregnant women over 16 years old and ≤20 weeks' gestation and have experienced a stillbirth or a neonatal death of any previous baby.
- Partners, approached through the woman after she has agreed *(a partner's unwillingness to participate will not affect the woman's continued participation).*
- Booked and planning have antenatal care at East Lancashire Hospitals NHS Trust or Pennine Acute Trust.

- For feasibility, sufficient command of English to participate in interviews and complete questionnaires will be required. Translation of materials will be explored with the aim of including parents lacking fluency in English in the definitive trial.

6.1.2. Health workers:

- Midwives, obstetricians, service managers directly/indirectly involved in providing care to women participating in the study.

6.2. Exclusion Criteria:

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

6.3. Recruitment:

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 midwives. Recruitment will be supported by NHS site service support infrastructure within the maternity services at both sites. 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:

Eligible pregnant women will be identified and approached via a member of the clinical care team 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 passed to the research midwife. The research midwife will contact the woman as agreed and provide a verbal explanation of the study supported by a written information sheet (e.g. by email. 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/he agrees a convenient date/time/place will be agreed for the initial meeting with the research midwife to complete the consent form. 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. It is anticipated that not all women and partners taking part in the study will be willing or available to participate in interviews. To ensure recruitment targets are met the willingness of all participants to be interviewed after the birth will be ascertained at recruitment.

6.3.2. Health professionals

Midwives, obstetricians and service managers who have involvement in providing care for women participating in the research 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 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 professional agrees to participate, a date, time and venue will be arranged for the interview, the consent form will be completed at this meeting.

6.4. Participants who withdraw consent:

At the point of recruitment all 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 sent for publication.

7. OUTCOME MEASURES

The primary outcomes for feasibility will be recruitment and retention of women and their partners in the study.

Secondary outcomes will include:

- Experiences of study participation and the intervention of parents and healthcare staff to determine the acceptability of trial processes and of the intervention.
- The characteristics of proposed psychological, cost-effectiveness, utility and clinical outcome measures will be examined in preparation for a definitive trial.
- Elements of process evaluation will assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors impacting on outcomes.

This study will inform the design of a UK-wide cluster randomised trial to test the impact and cost-effectiveness of the intervention on a range of clinical, psychological and health economic outcomes, potential funding will be sought under the NIHR Health Services and Delivery Research Programme (HS&DR).

8. DATA COLLECTION, SOURCE DATA AND CONFIDENTIALITY

8.1. Participant Log

A log of women who fulfil the eligibility criteria, women (and partners) 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 and health professionals 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. Women will meet with research midwife coordinator and or research assistant at recruitment (≤ 20 weeks), 30-37 weeks gestation and 4-6 weeks after the birth.

8.2. Demographic, clinical outcome 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 according to ONS criteria [37] socioeconomic status [highest level of

education, occupation]) medical (history, body mass index, smoking status, medication use) and obstetric history (previous pregnancies, mode of birth, outcomes) at recruitment. Index pregnancy data, including all healthcare service utilisation (planned and unplanned contacts with maternity and primary care) during pregnancy and the postnatal period, antenatal complications and any hospital admission, onset of labour, mode of birth, maternal and infant outcomes, length of hospital stay, infant feeding and postnatal complications up to transfer of the woman and baby to primary care (usually by 28 days postnatal). Data will be collected at recruitment, late pregnancy 30-37 weeks gestation) and 4-6 weeks post-birth (study completion).

8.3. Intervention Log

An investigator designed intervention log, completed by the care co-ordinator and research midwife after contacts, will capture which components of the intervention were implemented, how often, when and by whom.

8.4. Health Economics

EQ-5D-5L, comprising 5 dimensions with 5 levels and a visual analogue scale (Herdman et al. 2011) will be used to assess health status for women and partners at recruitment, 30-37 weeks and 4-6 weeks after birth and to construct quality-adjusted life years (QALYs) based on health status. Associated utility tariffs for England will be used to calculate quality adjusted life years (QALYs) during the study period from the EQ-5D-5L. Guidance from NICE regarding which utility tariff to use for the 5-level version of the EQ-5D is currently under review. Whichever tariff is recommended at the time of analysis will be used. For participants in both treatment groups, data will be collected from handheld maternity notes to identify the pregnancy-related healthcare resources used. Intervention logs completed by care co-ordinators will be used to identify the additional resources required to implement the intervention. The cost of the intervention and standard care will be estimated using the most recently published NHS resource costs database at the time of analysis. The feasibility of collecting data relating to other healthcare resources used will be explored. The completeness of data and descriptive statistics will be summarised for QALYs and healthcare resource use.

8.5. Psychological Assessment Questionnaires

Questionnaire booklets will be issued to women and partners, at recruitment, 30-37 weeks gestation and 4-6 weeks after birth including the following validated self-report tools:

- **Generalised Anxiety Disorder 7 item scale (GAD-7)**; A 7-item scale for screening for anxiety disorders. GAD-7 is used widely to assess generalised anxiety in a variety of settings including pregnancy and the postnatal period (Simpson et al., 2014) and will be completed by women and partners at recruitment, 30-37 weeks and 4-6 weeks after the birth.
- **Cambridge Worry Scale** (CWS) a 16-item content based measure (Green et al., 2003) specifically developed to examine the extent and content of worries in pregnancy will be completed by *women only* at recruitment and 30-37 weeks gestation.
- **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 (Cox et al., 1987; Murray and Carothers, 1990) will be completed by *women only* at recruitment, 30-37 weeks and 4-6 weeks after birth.
- **Maternal-Infant Bonding scale** (MIBS) an 8-item scale assessing the feeling of the mother towards her baby will be completed by *women only* at 4-6 weeks after the birth(Taylor et al., 2005).
- **Maternal Self Efficacy Scale,** (MSES) an 8-item scale to assess women's self-belief in their abilities to meet the needs of their infant, will be completed by women at 4-6 weeks after birth (Teti et al 1991).

8.6. Qualitative Data

Semi-structured, face to face or telephone interviews will be conducted with a subsample of women participants across both clinical sites, 4-6 weeks after the birth data. These will capture pregnancy, birth and postnatal experiences, including impacts of the intervention. Separate interviews with partners will explore experiences of supporting women and of the intervention.

Health professionals involved in the antenatal, intrapartum and postnatal care of participating women, including the midwife care-coordinators, obstetricians and service managers will be interviewed at the end of the intervention phase. These data

will provide insights into local context and identify barriers/facilitators to planned implementation.

Interviews will be conducted at the participant's preferred venue (home, private room in the hospital), using topic guides) audio-recorded with consent and transcribed verbatim using a University-approved transcription service.

Women will also be provided with a diary to allow recording of additional insight into daily/weekly thoughts, feelings and perceptions of care. A midwife researcher will co –facilitate monthly support group sessions and with consent of participants conduct participant observation in a sample of sessions to explore social processes, behaviours and interactions. Initially, 2-3 unfocussed observations will be conducted with detailed field notes taken to capture events. The field notes will be used to develop an organisational coding frame for more focussed recording of 10-12 sessions over both sites to supplement interview data.

9. DATA ANALYSIS AND STATISTICAL CONSIDERATIONS

9.1. Data Analysis

9.1.1. Recruitment and retention: Participant log data will be used to assess recruitment to targets and retention rates. A definitive trial would be considered feasible if recruitment targets were met and a rate of ≥75% retention achieved. Interview data will clarify possible barriers to recruitment and retention, which can be addressed in preparation for a definitive trial.

9.1.2. Experiences of participation, usual care and the fidelity and quality of implementation of the intervention will be explored through analysis of the intervention log, interviews, diaries and observation field notes using an inductive approach. Thematic analysis conducted in six recursive phases (Braun and Clarke, 2006), using multiple analysts to ensure credibility; will establish participants' views and experiences of recruitment, usual care in the control phase, components of the intervention including care co-ordination and the support sessions. Data will also help determine 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, midwives delivering the intervention and other professionals involved in parent's 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, health utility, clinical and resource utilisation 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 and health utility tools will be compared to determine whether characteristics are comparable across different measures. Analysis will focus on the estimation of confidence intervals for differences between the groups and estimation of variances to inform the design of the definitive trial.

9.2. Sample Size:

A formal power calculation is not appropriate for a feasibility study, therefore the total sample size of 60 women (±partners) has been determined pragmatically according to the accepted criteria for feasibility studies (Whitehead et al., 2016). These numbers will allow implementation of the pathway on a realistic scale in two settings and estimation of recruitment, fidelity and retention rates.

Previous experience with similar nested qualitative interview studies indicates up to 12 women and 8 partners participating during the control phase and up to 25 women and 12 partner participating in the intervention phase will be needed to achieve data saturation (O'Brien et al., 2013). Similarly for the health professional interviews, a total sample of up to 15 professionals, across both sites will be needed (Briscoe et al., 2015).

10. DATA MONITORING AND QUALITY ASSURANCE

10.1. 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. A study Technical Support Group will be convened with an independent chair and including the Dr Mills (Chief Investigator), Professor Lavender (Senior Researcher/Mentor), Independent Experts (to be appointed), Representatives of MASHC CTU and service user representatives (to be confirmed). This group will meet in prior to the start of the study, at the end of year 1, end of year 2 and prior to end of study in year 3. This group will review the study protocol and any amendments,

receive progress updates, advice on issues arising with the study conduct and design of the definitive trial.

The study will be managed by Dr Tracey Mills (Chief Investigator) with support from Professor Lavender. The research midwife (to be appointed) will be responsible for day to day co-ordination of trial activity from month 1-month 30 supervised by Dr Mills, Cathie Melvin (PI for ELHT) and Rachel Newport (PI for PAT) Meetings between the CI and Research co-ordinator will be held at least 2 weekly during this period. The research team, including all co-applicants and the research co-ordinator/research assistant (when appointed) will meet bi-monthly to review progress and compliance with research governance.

10.2. Roles

10.2.1. Research Team

Dr Tracey Mills: Chief Investigator responsible for overall study management, research governance, supervision of the research co-ordinator. Co-lead for patient and public involvement, training and supervision for delivery of the intervention, qualitative and clinical analysis, interpretation, and dissemination.

Professor Dame Tina Lavender: Mentor to the Chief Investigator Dr Mills, who has not previously led an intervention study on this scale. Advise on project management, research governance, data analysis, interpretation, presentation and dissemination.

Dr Debbie Smith: Train facilitators to deliver the 'coping-strategy toolbag', support analysis/interpretation of psychological outcome measures, qualitative data interpretation and reporting.

Dr Steve Roberts: Supervise analysis of the quantitative data, provide statistical advice and guidance for the design of the definitive trial.

Dr Elizabeth Camacho: Supervise health economics and cost-effectiveness components; provide guidance to the research assistant responsible for the data collection, analysis and reporting.

Dr Alex Heazell: Advise on obstetric/clinical aspects of the study including selection of clinical outcomes for the main trial and interpretation of qualitative and quantitative data, reporting and dissemination.

Cathie Melvin: Principle investigator for East Lancashire Hospitals NHS Trust, supervision of research midwife study co-ordinator

Rachel Newport: Principle Investigator for Pennine Acute Trust, supervision of study research midwife co-ordinator.

Claire Storey: Service User, Co-lead for public and patient involvement development of study material, the support group programme. Support with interpretation of qualitative data and dissemination.

10.2.2. Technical Support Group: To be confirmed.

10.3. Safety Reporting: Adverse Event definitions and reporting

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

10.3.1. 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(Health Research Authority, 2015).

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

Common pregnancy related complications:
Anaemia defined as haemoglobin level <110 g/L at booking, <105 g/L in 2nd and 3rd trimesters, <100 g/L postpartum (Pavord et al., 2012).
Hypertension
New onset/gestational diabetes
Small for gestational age fetus (Estimated fetal weight <10th centile by ultrasound)
Fetal malpresentation
Vaginal bleeding/APH/ placenta praevia identified on ultrasound scan
Premature rupture of membranes
Bacterial or viral infection
Labour related complications including: 3rd or 4th degree perineal tear, postpartum haemorrhage

Common neonatal complications

Jaundice
Feeding problems
Bacterial or viral infections

Psychological instruments

GAD-7 and EPDS are validated instruments for screening for generalised anxiety (pregnancy and general population) and depression and low mood (during pregnancy and the postnatal period), respectively. GAD-7 is calculated by assigning scores of 0, 1, 2 or 3 to the response categories, with a range from 0-21. Scores of 5, 10 and 15 represent cut-offs for mild, moderate and severe anxiety 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 GAD-7
- ≥10 on EPDS
- Score of 1 or above on item 10 of EPDS

Raised GAD-7 and 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 midwife or research assistant to the CI directly and in accordance with the adverse event protocol as above.

10.3.2. 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 Dr Tracey Mills (CI), Professor Dame Tina Lavender or Dr Alexander Heazell. (Health Research Authority, 2015)*

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

Pregnancy related complications:
Admission to hospital for anaemia.
Admission to hospital for hypertension.
Admission to hospital with new onset/ gestational diabetes
Admission to hospital for monitoring or care related to small for gestational age fetus (Estimated fetal weight <10th centile by ultrasound)
Admission to hospital with fetal malpresentation
Admission to hospital with vaginal bleeding/APH/ placenta praevia/premature rupture of membranes (identified clinically, or on ultrasound scan)
Admission to hospital for investigation or treatment of bacterial or viral infection
Admission to hospital for elective birth.
Prolongation of admission or readmission related to labour related complications eg perineal tears or PPH

Neonatal complications
Admission to hospital for jaundice
Admission to hospital with feeding problems
Admission to hospital with bacterial or viral infections

10.3.3. Recording and reporting:
Adverse events will be recorded in study documentation by the research co-ordinator, 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 Technical Support Group and the Sponsor.

Serious Adverse Events (other than those listed above) will be recorded on a SAE report form and reported by the research midwife co-ordinator to the CI as soon as possible after becoming aware (normally within 24 hours/ 1 working day).

SAEs will be reported to the to the Sponsor and Research Ethics Committee (REC) if in the opinion of Dr Tracey Mills, Professor Dame Tina Lavender, Dr Alexander Heazell or TSG chair (TBC) 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.

11. ETHICAL CONSIDERATIONS

Perinatal loss is an extremely sensitive area of maternity care with potential for women, partners, families and health professionals participating in research to suffer 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 increased risk of harm to bereaved parents and might offer some benefits (Hynson et al 2006). 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, interview schedules and diaries will be produced with input from Claire Storey and reviewed by service-users on the Technical Support group prior to use. A study-specific distress policy will be available and followed at all times, midwife care co-ordinators and research team midwives 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. Links will be established with local Professional Midwifery Advocates and support groups e.g. SANDS to signpost participants for additional support if required.

11.1. Data protection

Confidentiality will be maintained in accordance with Caldecott/NMC principles. NHS Trusts and The University of Manchester data protection policies will be followed and a study specific Data Management Plan compiled. All named investigators will have

training and experience in research governance procedures through Good Clinical Practice.

Identifiable data will be entered by the research midwife onto a password-protected database on a study specific area on the University Server via an encrypted NHS computer, paper copies will stored separately from other study data, in a locked cabinet, within a locked room. Only named members of the research team will have access to this database. To maintain confidentiality, participants will be allocated a unique study number at recruitment which will be used on all subsequent study data and materials. Interviews will be audio-recorded on an encrypted digital voice recorder and uploaded to the University server as soon as possible after completion. Participants will be invited to choose a pseudonym which will be used in transcription and verbatim quotations in published material associated with the study. Transcriptions will be performed by an external University approved transcription provider. Recordings will be deleted from the recorder after uploading and destroyed in the presence of two researchers, after publication of the findings. Research data, including transcripts will be kept for five years after completion of analysis. Study documentation and electronic study data will be stored securely at the East Lancashire NHS Trust, Pennine Acute Trust and transferred to University of Manchester server. Paper documentation and electronic study records will be transferred to the University of Manchester for archiving after completion of the study.

11.2. Ethical review

This study will require review by an NHS research ethics committee through the National Research Ethics Service (NRES). An application for ethical review of the study will be commenced as soon as funding is confirmed, using the Chief Investigator's existing allocated research time. All participant information and public facing materials will be reviewed by CS and service users from the Stakeholder/PPI group prior to submission. The application will be submitted through the Integrated Research Application system (IRAS). The study sponsor will be The University of Manchester. A separate application for the study to be included in the NIHR Clinical Network Research Portfolio will be made; therefore NHS approval will be sought for each site through the National Institute for Health Research (NIHR) Coordinated System for gaining NHS Permissions (CSP). All approvals will be confirmed prior to commencing the study in month 1. The study will be conducted in full conformance with principles of the "Declaration of Helsinki", Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research.

11.3. Researcher safety:

Data collection will involve episodes of lone working, to minimise the risk to researchers a project risk assessment will be conducted prior to commencing data collection. The Division of Nursing, Midwifery and Social Work, Fieldwork Guidance will be followed at all times including use of SkyGuard MySOS lone worker device. All researchers undertaking Lone Working will undertake University Lone Working training and updates as required.

12. 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.

13. FUNDING

This study is supported by a National Institute for Health Research (NIHR) Research for Patient Benefit (RfPB) Award PB-PG-0416-20003

14. PUBLICATION POLICY

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

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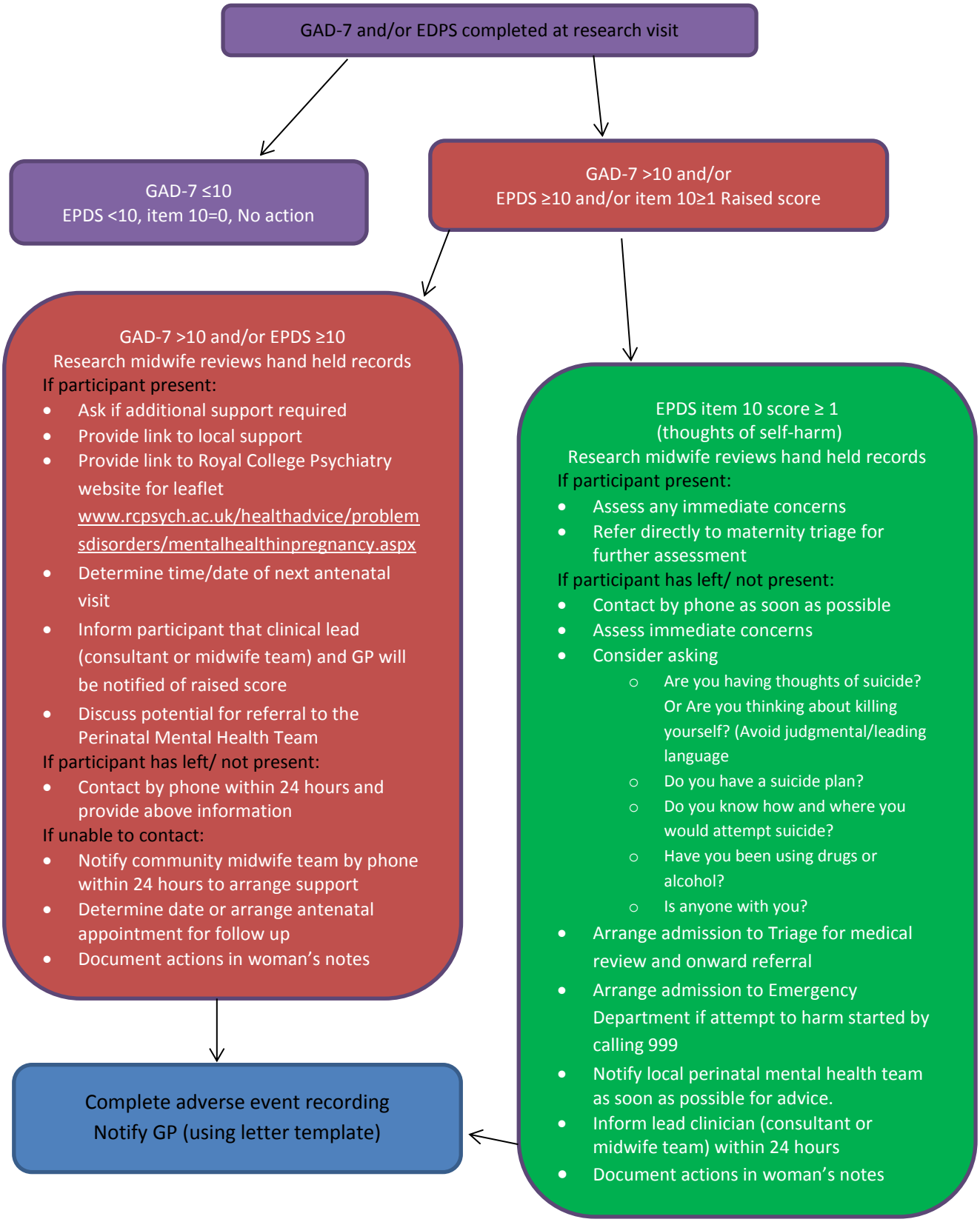
Appendices

Appendix 1: Response to raised GAD-7 or EDPS Scores (Pregnant or postnatal women) version 0



Appendix 2: Response to raised GAD-7 Scores (Partners) version 0.1