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Mothers working to prevent early stillbirth study (MiNESS 20–28): a case–control study protocol

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ABSTRACT

Introduction In the UK, 1600 babies die every year before, during or immediately after birth at 20–28 weeks' gestation. This bereavement has a similar impact on parental physical and psychological well-being to late stillbirth (>28 weeks' gestation). Improved understanding of potentially modifiable risk factors for late stillbirth (including supine going-to-sleep position) has influenced international clinical practice. Information is now urgently required to similarly inform clinical practice and aid decision-making by expectant mothers/parents, addressing inequalities in pregnancy loss between 20 and 28 weeks.

Methods and analysis This study focuses on what portion of risk of pregnancy loss 20–28 weeks' gestation is associated with exposures amenable to public health campaigns/antenatal care adaptation. A case–control study of non-anomalous singleton baby loss (via miscarriage, stillbirth or early neonatal death) 20^{+0} to 27^{+6} (n=316) and randomly selected control pregnancies (2:1 ratio; n=632) at group-matched gestations will be conducted. Data is collected via participant recall (researcher-administered questionnaire) and extraction from contemporaneous medical records. Unadjusted/confounder-adjusted ORs will be calculated. Exposures associated with early stillbirth at OR≥1.5 will be detectable ($p<0.05$, $\beta>0.80$) assuming exposure prevalence of 30%–60%.

Ethics and dissemination NHS research ethical approval has been obtained from the London—Seasonal research ethics committee (23/LO/0622). The results will be presented at international conferences and published in peer-reviewed open-access journals. Information from this study will enable development of antenatal care and education for healthcare professionals and pregnant people to reduce risk of early stillbirth.

Trial registration number NCT06005272.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This case–control study is able to examine the association of multiple modifiable exposures during pregnancy with pregnancy loss between 20 and 28 weeks.
⇒ Case definitions are independent of legal definitions, in keeping with parental experience of baby loss at this stage of pregnancy.
⇒ The random control identification process will ensure that control participants are reflective of the wider obstetric population.
⇒ Members of the public with relevant lived experience of both pregnancy loss and healthy pregnancy have been involved in the conceptualisation and design of the study.
⇒ Recall bias may be significant among bereaved participants who may seek to make sense of their experiences.

INTRODUCTION

Stillbirth, the death of a baby before or during birth, is associated with adverse psychological, social and economic outcomes for the mother, their partner, their wider family and society.[1] UK stillbirths cost >£27.2 million/year in healthcare, workplace absence and funeral costs alone.[2] Reducing stillbirth and neonatal death is an international target for 194 countries,[3] a specific priority for the UK Government[4] and primary concern for parents and families.[5 6] To prevent these deaths, it is important to understand modifiable risk factors for baby loss.

In the UK, stillbirth (legally defined as death before birth of a baby≥24 weeks' gestation) affects 4/1000 births (>2500/year). However, most high-income countries record stillbirth from 20 or 22 weeks' gestation. Baby death between 20 and 24 weeks' gestation (~750 UK deaths/year) has similar impact on parents' physical and psychological well-being.[7] Additionally, births at 20–22 weeks' gestation with signs of life are variously reported as stillbirths or neonatal deaths.[8] Therefore, in this study, we shall examine baby deaths occurring between 20 and 28 weeks' gestation, occurring before or during labour or immediately after birth. For consistency, these baby losses (legally second trimester miscarriages, stillbirths and

neonatal deaths) will be referred to here as 'early stillbirth', in line with parents' wishes.[7]

Efforts to reduce stillbirth principally focus on deaths occurring after 28 weeks' gestation. By understanding those at greatest risk of late stillbirth, effective healthcare interventions have been rolled out across England[9] and internationally.[10] The Midlands and North of England Stillbirth Study (MiNESS) identified associations between supine sleep position and other potentially modifiable exposures and stillbirth≥28 weeks' gestation.[11–15] It informed national and international education campaigns and policy, and sleep position recommendations for pregnant people have been incorporated into NHS England Saving Babies Lives Care Bundle V.3[16] and National Institute for Health and Care Excellence antenatal care guidelines.[17] Dissemination of information about such modifiable factors in late pregnancy may be partly responsible for the 15% UK reduction in late stillbirth from 2014 to 2018.[18]

Critically, there has been no reduction in stillbirths occurring before 28 weeks (~40% of losses equivalent to ~1600 babies/year). Efforts to prevent early stillbirth are limited by a significant proportion of these deaths having no clear identified cause. Approximately 3:1000 pregnancies in the UK and similar countries end in early stillbirth/early neonatal death; of these ~10% are due to congenital anomalies, ~30% due to preterm labour or antepartum haemorrhage, ~20% are unexplained and the remainder were attributed to a variety of perinatal conditions.[19] Due to maternal and fetal physiological differences between the middle and last trimester of pregnancy, known risk factors for late stillbirth (such as supine sleep position or reduced fetal movement) may not associate with early stillbirth (at all, or to the same extent), and as yet unrecognised independent risk factors for early stillbirth may exist, for example, those that may perturb the vaginal microbiome or result in cervical weakness.

A systematic review suggested caffeine consumption≥300–350 mg/day in pregnancy was associated with increased risk of pregnancy loss and late stillbirth.[14 20] However, only 2/14 studies included second trimester pregnancy loss. The association between reduced fetal movements and stillbirth≥28 weeks' gestation is well established.[13 21] However, 20% of pregnant people presenting with reduced fetal movements do so <28 weeks' gestation at a time when many pregnancies have not yet established a regular pattern of movement.[22] Six observational studies demonstrate an association between going-to-sleep position and risk of stillbirth≥28 weeks' gestation.[23] However, the impact of supine going-to-sleep position on early stillbirth is unknown; the NuMom2b cohort suggested no relationship with early stillbirth but was underpowered (24 stillbirths/8706 participants)[24]; a relationship between supine sleep position and early stillbirth remains biologically plausible.[25] However, extrapolating data from earlier/later pregnancy studies may lead to over or underinvestigation or intervention in the midtrimester.

Information about modifiable factors associated with early stillbirth is now urgently required to inform clinical practice, to assist expectant mothers/parents to reduce their baby's risk of stillbirth and to help address inequalities in pregnancy outcome. This study hypothesises that early stillbirth between 20 and 28 weeks is associated with both similar, and novel, potentially modifiable factors during/before pregnancy. These factors may include 'exposure' factors (eg, diet, sleep characteristics, physical activity), 'inequality' factors (ethnicity, deprivation or exposure to domestic violence) and 'healthcare' factors (eg, lifestyle advice, screening/care provided, medical management). Further, the study will assess what portion of early stillbirth risk may be mitigated by facilitating positive health exposures among expectant mothers/parents and their partners, or by adaptation of their environment or healthcare provision. Information obtained from this study will enable antenatal care and education to be developed to reduce the risk of early stillbirth.

METHODS AND ANALYSIS

This study addresses the research question 'Is early stillbirth associated with modifiable factors?' It specifically aims to:

1. Identify modifiable risk factors for early stillbirth that are amenable to public health campaigns or adaptation of antenatal care.
2. Confirm or refute whether the range of factors associated with late stillbirth are independently associated with early stillbirth, including (but not limited to) supine sleep position, caffeine intake and reduced fetal movement.
3. Explore interactions between maternal/parental characteristics (especially those relating to health inequalities including ethnicity and socioeconomic deprivation), fetal factors (including fetal growth restriction, reduced fetal movements) and early stillbirth risk.
4. Determine whether exposures associated with early stillbirth vary by cause of death.

Study design

A prospective case–control study of people who experience early stillbirth and those who have a contemporaneous ongoing pregnancy at the same gestation will be conducted. The methodology of the previous MiNESS study[26] has been adapted for application to early stillbirth in a multicentre study taking place in 40–60 UK maternity units. Participating sites are welcomed from around the UK including urban or rural location, varying size and level of on-site maternity/neonatal care and university or non-university hospitals. The study is non-interventional; there is no change to the standard care provided to bereaved or pregnant participants at participating sites.

A case–control study is the most appropriate, efficient, design to study relatively rare disorders such as stillbirths and can evaluate multiple exposures in the same study. Routine data studies lack detailed information

regarding pregnancy exposures (eg, sleep practices, caffeine consumption). Individuals with gestation and time-matched ongoing pregnancies are the appropriate comparator group for cases of early stillbirth as the parental objective is ongoing pregnancy rather than live preterm birth.

Manchester University Hospital Foundation Trust is the research sponsor (Ref B01875; research.sponsor@mft.nhs.uk). The study was peer reviewed and funded by the National Institute for Health and Care Research. The funder and sponsor have no role in study design, data collection and analysis or publication. The sponsor representative is a member of the trial management group. The trial was registered at ClinicalTrials.gov on 16 August 2023 (NCT06005272); protocol V.1.4 (18 October 2023) was implemented on 20 October 2023 (protocol amendments will be version controlled and updated on ClinicalTrials.gov). Recruitment commenced on 1 September 2023 and will continue until 31 August 2025. Initial results will be available from March 2026.

Sample size

Early stillbirth occurs in ~0.3% of births.[24] Recruiting 316 cases and 632 controls will detect associations between early stillbirth and exposures of interest with an OR≥1.5 with 80% power and 5% significance level, where 30%–60% of participants are exposed. Individual early stillbirth subtypes (preterm delivery, unexplained in utero, explainable in utero) are expected to occur in a 1:1:1 ratio. If these are differentially affected by certain exposures, associations with an OR≥2 will be detectable. Larger effect sizes are expected in relation to subtype-specific risk factors due to reduced patient heterogeneity.

Inclusion and exclusion criteria

Overall inclusion criteria: people receiving pregnancy care and/or giving birth in a singleton pregnancy, between 20 and 28 weeks of pregnancy in a participating maternity unit during the study period. Case participants are defined as those where baby was diagnosed to have died before/during or immediately after labour between 20^{+0} and 27^{+6} weeks of pregnancy. Control participants are defined as those with an ongoing pregnancy at a group-matched gestation.

Overall exclusion criteria: (1) Presence of a known significant congenital anomaly; pregnancies where significant congenital anomaly is diagnosed after participation will be excluded from data analysis. (2) Inability to consent despite provision of translation services. (3) Participant age<16 years. For case participants: Attempted postnatal transfer of the infant to neonatal services (survival-focused care).

Participant recruitment

Figure 1 depicts the proposed flow of participants through the study. All pregnant people receiving care in participating hospitals will be made aware of the study prior to any approach, by awareness leaflets, posters and/or inclusion of study information on hospital websites/social media pages. All bereaved mothers/birthing parents who experience early stillbirth in the current pregnancy at a participating maternity unit will be approached by a member of their clinical care team; initial introduction to the study by a clinician known to the participant was viewed favourably by participants in MiNESS.[27] Potential control participants will be identified from maternity units' patient lists using bespoke random identification algorithms (based on local historic 'case' gestation mix); this ensures all pregnant people receiving care at participating maternity units will have equal chance of being invited to participate as a control. Eligibility will be assessed by the local care team prior to approach. A 50% recruitment rate in both groups is anticipated.

Data collection

The research midwife will obtain informed consent to participate and administer a bespoke study questionnaire,[27] facilitated by use of interpreter if required. Copies of the study information sheets and consent form are provided in the online supplemental materials 1–3. Informed consent includes deposition of anonymised study data in publicly available research data repositories. The questionnaire is adapted from the questionnaire used in the original MiNESS study[28] and captures data on the social and demographic characteristics of the participant and any partner, past obstetric and medical history, medication and supplement use, use of nicotine/tobacco products, alcohol, recreational substances or caffeine, stress, violence and sleep practices. It includes two standardised psychometric questionnaires: perceived social stress scale[29] and multidimensional scale of perceived social support.[30] New questions have been added to consider factors that may alter cervical strength, the vaginal microbiome, the role of SARS-CoV-2 infection/vaccination and to further understand the impact of health inequalities including ethnicity and socioeconomic deprivation (including self-assessed verbal and written language proficiencies and use of interpretation services). The interview and questionnaire are conducted only once.

We aim to interview all participants as close to the interview reference date (date of early stillbirth diagnosis for case participants or randomly allocated gestation for control participants), but no more than 6 weeks after this date, to aid recall accuracy and to minimise the impact of recall bias among bereaved participants. It is not possible to blind research midwives to pregnancy viability. The same questions will be posed in a standardised manner to both case and control participants; standardised follow-up questions will quantify exposure magnitude/timing. Following interview, the local research team will extract routinely recorded data from contemporaneous medical records (maternal biometry, antenatal and post-mortem investigation results, healthcare episodes). There is no further participant activity in the study after interview and no safety incidents are anticipated. Participants

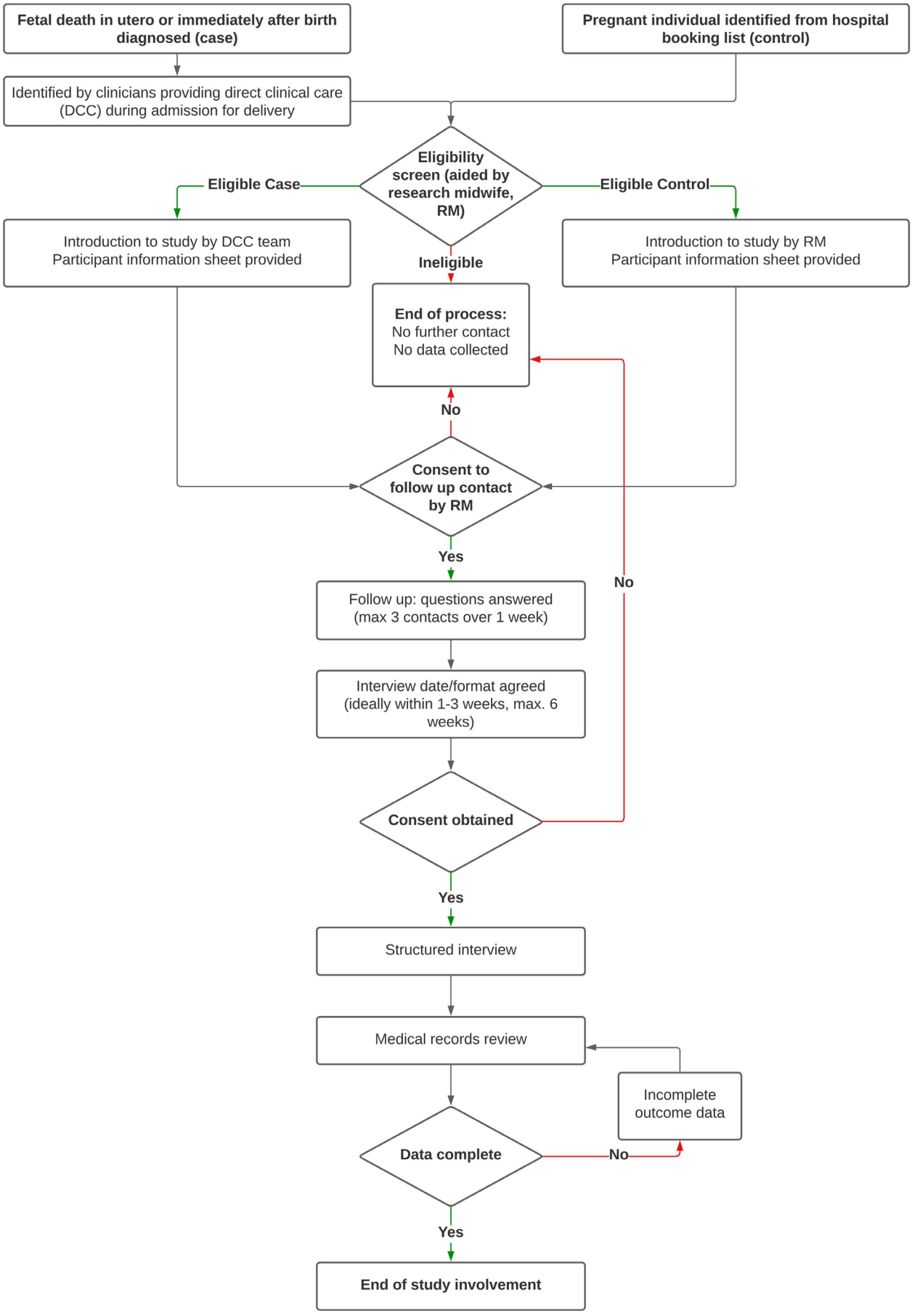

Figure 1 Proposed flow of participants through the study. DCC, Direct clinical care; RM, Research midwife.

who withdraw from the study after interview (but before full outcome data is collected from case note review) will not be replaced; data already collected will continue to be used. All data will be collected via, and stored on, restricted access REDCap electronic case report forms during the study data collection period. Electronic case report form (eCRF) responses are restricted to predefined options or have in built data validation rules in order to promote data quality. Six-monthly local data quality audit will be performed, as well as annual sponsor audit of protocol compliance. A copy of the study data management plan is available on request.

Statistical analysis

As a case–control study examining the association of multiple exposures with early stillbirth a data monitoring committee and interim analyses are not appropriate. On study completion, the data will be immediately fully anonymised. Access to the preanonymised final dataset will be restricted to the chief investigator and the study sponsor. Missing data will be assessed, incorporated and reported in line with recent guidance from the Strengthening Analytical Thinking for Observational Studies Initiative.[31] Unadjusted and adjusted associations between the outcome (all-cause early stillbirth) and each exposure will be estimated by logistic regression. A bespoke adjustment set will be used for each exposure variable.[32] All models will include age, first pregnancy, self-declared ethnic group, smoking, obesity, diabetes and hypertension. Secondary analyses will be conducted by early stillbirth subtype (preterm delivery, unexplained in utero, explainable in utero) and repeated including only babies without sign of life after birth. Fully anonymised individual patient data will be made available, along with the metadata required for its interpretation, via an online research data repository on publication of the primary research findings.

Patient and public involvement (PPI)

The study question (identification of modifiable risk factors for baby loss) was posed by stakeholders including bereaved parents/family members, in the James Lind Alliance stillbirth and miscarriage priority setting partnerships.[5 6] A study-specific PPI group with relevant lived experience helped to refine the study question and advise on study design including acceptability and relevance of proposed study questions, and wording of public facing study materials, including making a study-specific information video. Parent-experts, along with charitable stakeholders and international stillbirth research experts, will oversee the delivery of the study through a study advisory group.

ETHICS AND DISSEMINATION

Ethical approval has been obtained from the London—seasonal research ethics committee. The principal ethical concern is the potential for (attempted) recruitment to the study to cause or exacerbate distress among bereaved or pregnant parents. Individuals approached to take part as control participants may fear 'tempting fate' and may experience distress in relation to mention of the potential of stillbirth. Researchers will uphold the dignity of (potential) participants at all times and provide support. Feedback from participants in the original MiNESS, Auckland stillbirth and Sydney stillbirth studies indicates that participants appreciated taking part in the research; non-participants also viewed the invitation to participate in the research positively.[28 33]

The study findings will be disseminated through international conferences and peer reviewed open access publications. Public information campaigns will be designed in conjunction with the study PPI group and charitable stakeholders in a manner similar to that of the original MiNESS study.

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Contributors LH wrote the study protocol and manuscript. JW designed the statistical analysis plan, edited the protocol and manuscript. AEH conceptualised the study, edited protocol and manuscript. RKM, NS, LKS, CS and TS provided intellectual input in study design. All authors read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods and analysis section for further details.

Patient consent for publication Not applicable.

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