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SYSTEMATIC REVIEW

Interventions, outcomes and outcome measurement instruments in stillbirth care research: A systematic review to inform the development of a core outcome set

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Abstract

Background: A core outcome set could address inconsistent outcome reporting and improve evidence for stillbirth care research, which have been identified as an important research priority.

Objectives: To identify outcomes and outcome measurement instruments reported by studies evaluating interventions after the diagnosis of a stillbirth.

Search strategy: Amed, BNI, CINAHL, ClinicalTrials.gov, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Embase, MEDLINE, PsycINFO, and WHO ICTRP from 1998 to August 2021.

Selection criteria: Randomised and non-randomised comparative or non-comparative studies reporting a stillbirth care intervention.

Data collection and analysis: Interventions, outcomes reported, definitions and outcome measurement tools were extracted.

Main results: Forty randomised and 200 non-randomised studies were included. Fifty-eight different interventions were reported, labour and birth care (52 studies), hospital bereavement care (28 studies), clinical investigations (116 studies), care in a multiple pregnancy (2 studies), psychosocial support (28 studies) and care in a subsequent pregnancy (14 studies). A total of 391 unique outcomes were reported and organised into 14 outcome domains: labour and birth; postpartum; delivery of care; investigations; multiple pregnancy; mental health; emotional functioning; grief and bereavement; social functioning; relationship; whole person; subsequent pregnancy; subsequent children and siblings and economic. A total of 242 outcome measurement instruments were used, with 0–22 tools per outcome.

Conclusions: Heterogeneity in outcome reporting, outcome definition and measurement tools in care after stillbirth exists. Considerable research gaps on specific intervention types in stillbirth care were identified. A core outcome set is needed to standardise outcome collection and reporting for stillbirth care research.

KEYWORDS
core outcome set, patient and public involvement, stillbirth, stillbirth care, systematic review

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See Appendix 1 for iCHOOSE Collaborative Group members.

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1 | INTRODUCTION

In 2019, an estimated 2 million babies were stillborn.[1] Previous research has documented the devastating negative medical, social and psychological impact of stillbirth on families.[2,3] Studies have found that the care parents receive after the diagnosis stillbirth is inconsistent and often suboptimal.[4,5] There is a consensus among the stillbirth research community and bereaved parents that there needs to be more evidence-based care available to improve care following stillbirth for families worldwide.[4,6,7]

There is a range of potential interventions that tackle different aspects of care after a stillbirth across the life course, from the initial diagnosis of the death of a baby, bereavement care and interventions to understand why a baby has died, to long-term psychosocial support and care in a subsequent pregnancy. Cochrane reviews exploring these aspects of care have unanimously found few randomised controlled trials to guide clinical practice and improve care after a stillbirth has been diagnosed.[8–10] The lack of evidence is further compounded by heterogeneity in outcome reporting, leading to a difficulty in synthesising and appraising the results of previously conducted studies.

Perhaps it is unsurprising that heterogeneity exists, given the array of interventions available at different timepoints, addressing different aspects of the stillbirth. Nonetheless, it is important to identify and measure outcomes consistently when investigating mental, physical and social healthcare and impacts associated with the experience of stillbirth care.[2] This is particularly important in order to build a comprehensive evidence base on the interventions that are most likely to be effective. By developing a core outcome set, a minimum set of outcomes that should be collected and reported in a given study, the same outcomes could be measured using the same measurement tools, minimising outcome reporting bias.[11] Similar outcomes can therefore can be compared and combined, thus strengthening the evidence base and statistical power to inform best practice and improve care.[11]

An international survey in 2019 nominated the development of a core outcome set for stillbirth research as an important and urgent, top-five priority to inform clinical practice in a pregnancy subsequent to stillbirth.[12] The iCHOOSE study is addressing and expanding these priorities by developing a core outcome set for stillbirth care research.[13] Here we report on a systematic review that aims to identify what interventions and outcomes have been reported as an initial step in core outcome set development.

2 | METHODS

The systematic review was prospectively registered on PROSPERO International prospective register of systematic reviews (CRD42018087748) and adheres to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (see Appendix S2 for the PRISMA checklist).[14] The full protocol for the development of the core outcome set for stillbirth care research has been published elsewhere.[13]

2.1 | Study identification

As very few randomised trials of care after stillbirth exist, we felt it was necessary to include observational studies in our methods. This approach was designed to facilitate the development of a comprehensive long-list of potential outcomes for inclusion in a core outcome set for stillbirth care research. With assistance from a clinical librarian (KB), electronic searches of Amed, BNI, CINAHL, ClinicalTrials.gov, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Embase, MEDLINE, PsycINFO and WHO ICTRP databases were conducted with a date limit of 1998 to 2019, updated in August 2021. For pragmatic reasons, the research team decided to limit the search to a generation's worth of research data (approximately 20 years) to ensure results included seminal stillbirth care research and relevant contemporary outcomes. Free text and subject heading terms were searched, such as stillbirth, fetal death, perinatal mortality and fetal mortality, and methodological filters were applied. A detailed search strategy is included in Appendix S1. Reference lists of extracted articles and relevant systematic reviews were searched.

2.2 | Study eligibility

See Table 1 for inclusion and exclusion criteria for systematic review.

2.3 | Study selection process

The identified publications were uploaded to Covidence systematic review software and duplicates removed.[15] Prior to abstract and full-text screening, all review authors had training on the study's objectives, eligibility criteria and outcome extraction. All titles and abstracts were screened independently by at least two members of the review team (two of DB, AM, AD, CS, KB) with previous experience of systematic review methodology. Full text articles identified from the screening process were then assessed for eligibility by two reviewers. Due to the large number of studies, a team of reviewers were involved in the full text review and data extraction process (DB, AM, AD, CS, KD, KB, ES, AL, CB).

2.4 | Quality assessment

Risk of bias assessment was initially included in the protocol; however, quality assessment was not relevant in the context of identifying reported outcomes, as the aim of this study was to create a long-list of outcomes and identify outcome

TABLE 1 Inclusion and exclusion criteria for systematic review of interventions, outcomes and measurement instruments.

	Included	Excluded
Types of studies	• Randomised controlled trials • Non-randomised comparative and non-comparative studies (e.g. cohort, case–control, cross-sectional studies) • English-language studies	• Systematic reviews, case reports, editorials, review articles, abstracts, protocols and grey literature • Qualitative studies • Non-English language studies
Population	• Mothers, fathers, parents, children, siblings (including those bereaved siblings of stillbirth in a multiple pregnancy), and grandparents experiencing a stillbirth • Stillbirth in a singleton or multiple pregnancy • Studies including stillbirth from 20 weeks' gestation. Studies were not excluded based on the gestational age of stillbirth beyond 20 weeks, as the definition varies between countries. • No restriction by country worldwide (including high-, middle-, lower-income countries according to World Bank Lending Group definition[271])	• Miscarriage, neonatal death, termination of pregnancy • Note: an inclusive approach was adopted – studies were still included if they also included stillbirth and another type of pregnancy loss in their population of interest, e.g. perinatal death (stillbirth and neonatal death). Only stillbirth-relevant outcomes were extracted. • Pregnancy loss <20 weeks' gestation • Studies including healthcare professionals only as research and outcome measurement population
Interventions	• Any study evaluating an intervention (or type of care) following the identification of stillbirth • Immediate hospital interventions, e.g. induction of birth, mode of birth, standard hospital/bereavement care • Interventions for understanding the causes of stillbirth, e.g. clinical investigations, postmortem, parental engagement in the perinatal mortality review process • Interventions in the follow up period in the community, e.g. bereavement support, social support • Psychosocial interventions, e.g. counselling, psychotherapy, social support • Interventions in the inter-pregnancy interval to improve health optimization • Interventions in the subsequent pregnancy after stillbirth, e.g. medical. psychosocial, support	• Interventions prior to stillbirth being identified • Interventions for prevention of stillbirth (with the exception of interventions to prevent recurrence of stillbirth in a subsequent pregnancy after stillbirth) • Detailed histopathological or mechanistic molecular studies e.g. investigations of specific lesions in placentas, specific genetic abnormality or where main aim was not to identify cause of death
Outcomes	• Assessor- and patient-reported • Clinical/medical, care experience, psychological, social, economic, resource outcomes • Labour & birth, postpartum (within the first 6 weeks), within the first year, within the first 5 years (medium term), 5 years or more (longer-term outcomes) • Subsequent pregnancy after stillbirth outcomes, e.g. clinical or psychological outcomes specifically related to a subsequent pregnancy	• Studies that do not report an outcome following an intervention after stillbirth

measurement tools for stillbirth care research, not to synthesise any measured effect. Therefore, we do not report on risk of bias.

2.5 | Data extraction

Data were extracted into a standardised data extraction sheet using Google FORMS, which was directly input into a Microsoft EXCEL spreadsheet. The data extraction form was developed and piloted with members of the review team prior to its use. Extracted data were: basic publication details (author and date of publication); study setting; study population; details of intervention; study methodology; outcomes measured; their definition (if stated); their relevant outcome measurement tool (if applicable); and patient and public involvement in the research design. Outcomes were extracted verbatim from the published abstract, methods or results including tables. Data extraction from all publications was conducted by the primary author (DB) and team members conducted independent data extraction on 50% of these to ensure reliability of extraction. All disagreements were resolved through a third senior reviewer (CB).

2.6 | Classification and analysis of outcomes

Following data extraction, true duplicate outcomes were removed. Subsequently, to ensure methodological transparency, a further process was conducted whereby two reviewers (a clinician, DB and an experienced researcher, AD) organised and classified the outcomes into outcome domains independently using the Cochrane reviews and COMET core outcome set database taxonomy.[16] This organisation process allowed for

outcomes described using the same terminology to be identified and grouped together to enable identification of truly unique outcomes. The Cochrane reviews and COMET taxonomy had more clinical domains than required and therefore the outcomes were further grouped into an adapted stillbirth care research outcome taxonomy (Table S2).[16] The adapted taxonomy was created to better reflect the needs of stillbirth care research and was developed from ongoing qualitative research and bereaved parent input.

Similar interventions were grouped into the following categories: labour and birth care, postpartum bereavement care, investigations into causes of stillbirth, psychosocial support, multiple pregnancy and interventions in a subsequent pregnancy. Heterogeneity in outcome reporting was assessed in randomised controlled trials according to intervention category. We calculated the number of different definitions and outcome measurement tools described for an individual outcome. The frequency of outcomes assessed at specific time intervals post-stillbirth is reported. An infographic was produced to illustrate the types and timings of interventions after stillbirth (Figure 1).

2.7 | Patient involvement

Parents who experienced a stillbirth were involved in the design of the research question through to the analysis of the results and review of the manuscript. The parent involvement panel included 11 bereaved parents and had global representation (including Africa, Australasia, Europe, North America) through the iCHOOSE collaborative group.

3 | RESULTS

Our initial searches identified 21 893 records (Appendix S1). After excluding 6398 duplicate records, 15 495 titles and abstracts were screened. An additional 217 articles were identified from searching the reference lists of identified articles and relevant systematic reviews. A total of 1492 studies were included for full text review. Of these, 240 studies met the inclusion criteria, representing approximately 298 762 participants.[17–256]

See Table S1 for detailed characteristics of included studies and Appendix S3 for PRISMA flow diagram.

Studies from 64 different countries were included. A total of 183 studies conducted research in high-income, 24 from upper/middle income, 28 from lower-middle and five from low-income countries. The majority of studies were conducted in Europe (111 studies), followed by North America (52 studies) and Asia (42 studies). Only 23 studies included fathers in their interventions. Lastly, of 240 studies, only 10 involved patients and members of the public in the study

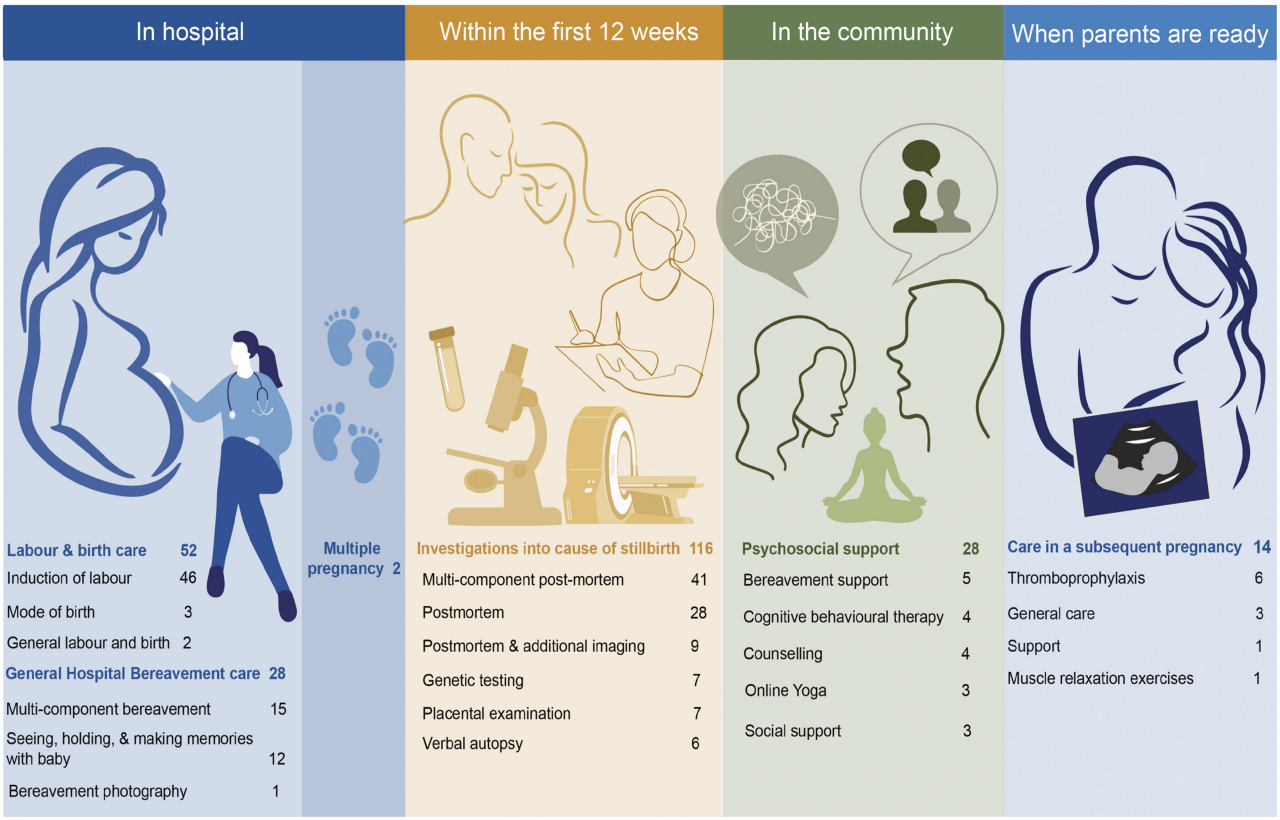

FIGURE 1 Types and timing of interventions for stillbirth care research. *Number illustrates number of studies. Infographic by Anni King, Senior Research Associate in Medical Imaging, Bristol, UK.

design and selection of their outcomes and/or outcome measurement tools. A summary of included study details is shown in Table 2. Fifty-eight different types of interventions were identified (Figure 1 and Table 2).

A total of 817 outcomes were reported; after de-duplication and classification of outcomes, 391 unique outcomes remained. The 391 unique outcomes were organised into 14 outcome domains (Table 3).

See Table S3 for a comprehensive list of outcomes reported across all studies, by outcome domain and study design. No outcome was reported in all studies of a specific intervention type. A further analysis of outcome reporting in randomised controlled trials (RCTs) only (Table S4) indicated variability in outcomes reported and no outcome was reported by every RCT of a specific type.

3.1 | Labour and birth care: Interventions and outcomes

Interventions included in this category were induction of labour (46 studies), mode of birth (3 studies) and neural axial analgesia (1 study). The five most commonly reported outcomes in studies reporting on labour and birth interventions were induction to birth interval, reported by 65% of studies (34 of 52 studies), complications or side effects of treatment, reported by 39% of studies (20 of 52 studies), successful induction, reported by 31% of studies (16 of 52 studies), use of analgesia during labour and birth, reported by 25% of studies (13 of 52 studies) and dose of misoprostol required, reported by 15% (8 of 52 studies). Only one study reported maternal death as an outcome of interest, and only two studies (4% of labour and birth interventions) reported satisfaction with intervention or care. No studies reported psychological (e.g. grief, anxiety) outcomes.

3.2 | Bereavement care: Interventions and outcomes

Fifteen studies were identified evaluating multiple components of bereavement care (e.g. at least two seeing and holding baby, making hand or footprints, photos and mementos, including children or family members in care, care or support from healthcare professionals). The greatest number of outcomes was reported within the delivery of care outcome domain (15 outcomes), followed by the emotional functioning domain (15 outcomes). The most frequently reported outcomes included experience of intervention or care reported by 32% (9 of 28 studies), depression reported by 29% (8 of 28 studies), anxiety reported by 21% (6 of 28 studies), post-traumatic stress disorder reported by 17% (post-traumatic stress disorder [PTSD], 5 of 28 studies) and grief reported by 18% (5 of 28 studies). No studies measured the impact of postnatal hospital care on parents, role, e.g. returning to work or parenting, or impact of care on existing older children.

TABLE 2 Study characteristics for included studies in the systematic review.

Types of intervention	Number of studies (n = 240)
Labour and birth care	
Induction of labour	46 (19.2%)
General labour and birth	2 (0.8%)
Mode of birth	3 (1.3%)
Neural axial analgesia	1 (0.4%)
General hospital/bereavement care	
Multi-component bereavement care[a]	15 (6.3%)
Seeing, holding and making memories with baby	12 (5%)
Bereavement photography	1 (0.4%)
Investigations to understand cause of stillbirth	
Multi-component postmortem investigations[b]	41 (17.1%)
Postmortem	28 (11.7%)
Postmortem & additional imaging	9 (3.8%)
Genetic testing	7 (2.9%)
Placental examination	7 (2.9%)
Verbal autopsy	6 (2.5%)
Postmortem imaging	4 (1.7%)
Minimally invasive autopsy and biopsy	3 (1.3%)
Testing for thrombophilia	3 (1.3%)
Antinuclear antibody test	1 (0.4%)
Educational programme for professionals and multi-component investigations	1 (0.4%)
Genetic counselling	1 (0.4%)
Kleihauer–Betke testing	1 (0.4%)
Parental engagement in the perinatal mortality review	1 (0.4%)
Perinatal death clinical investigation tool	1 (0.4%)
Perinatal Death Surveillance and Response (PDSR) system	1 (0.4%)
Perinatal mortality review	1 (0.4%)
Stillbirth in a multiple pregnancy	
Bereavement care for stillbirth in a multiple pregnancy	1 (0.4%)
Intrauterine rescue transfusion	1 (0.4%)
Psychosocial support	
Bereavement support intervention	5 (2.1%)
Cognitive behavioural therapy	4 (1.7%)
Counselling	4 (1.7%)
Online yoga	3 (1.3%)
Social support[d]	3 (1.3%)
Internet peer support group	2 (0.8%)
Support groups	2 (0.8%)
Intergenerational bereavement programme	1 (0.4%)
Interpersonal psychotherapy	1 (0.4%)
Massage	1 (0.4%)
Mindfulness	1 (0.4%)
Occupation-based retreat	1 (0.4%)
Care in a subsequent pregnancy	
Thromboprophylaxis in a subsequent pregnancy	6 (2.5%)
General care in a subsequent pregnancy	3 (1.3%)
Intravenous immunoglobulin in a subsequent pregnancy	1 (0.4%)

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TABLE 2 (Continued)

Types of intervention	Number of studies (n = 240)
Maternity waiting home[c]	1 (0.4%)
Muscle relaxation exercises	1 (0.4%)
Psychoeducation	1 (0.4%)
Support intervention in a subsequent pregnancy	1 (0.4%)
Total number of participants	**~298 762**

Study characteristic	Number of studies (n = 240)
Number of randomised control trials	40 (16.7%)
Number of observational studies	200 (83.3%)
Number of unique countries	64 (26.7%)
Studies by region	
Europe	111 (46.3%)
North America	52 (21.7%)
Asia	42 (17.5%)
Oceania	16 (6.7%)
Africa	13 (5.4%)
International	5 (2.1%)
South America	1 (0.4%)
World Bank Lending Group[e]	
High-income	183 (76.3%)
Lower-middle-income	28 (11.7%)
Upper/middle-income	24 (10%)
Low-income	5 (2.1%)
Number of fathers	23 (9.6%)
Number of patient & public involvement	10 (4.2%)
Year published	
1998–2001	27 (11.3%)
2002–2005	35 (14.7%)
2006–2009	41 (16%)
2010–2013	48 (20.2%)
2014–2017	53 (21.8%)
2018–2021	38 (16%)

[a]Multi-component bereavement care – including at least two of the following intervention or care variables: sensitive care during labour and delivery, mode of birth, time spent with baby, seeing and holding baby, hand/footprints, photos and mementos, including children or family members in care, care or support from healthcare professionals and services, e.g. doctor, bereavement midwife, chaplain, anaesthetist interactions, postmortem investigations, grief support, care after birth, having a funeral, post-natal appointments, hospital-based counselling, family support.

[b]Multi-component postmortem investigations – including at least two of the following investigations or care variables. Review of the medical and obstetrics history, postmortem pathological examination, placental examination, postmortem radiographs, postmortem MRI, laboratory blood testing for mother or baby (e.g. congenital infections, diabetes, auto-antibody testing, thrombophilia testing, biochemistry), microbiological testing, virology, genetic testing, counselling, perinatal mortality review.

[c]Maternity waiting home – A maternity waiting home is a residential facility located near a medical facility, where 'high risk' women can await their delivery to 'bridge the geographical gap' in obstetric care between rural areas with poor access to services.[15]

[d]Social support – including at least two of the following support from hospital, doctor, partner, family, friends, work, parent support groups.

[e]Region – World Bank Lending Group.[271]

3.3 | Investigations to understand cause of stillbirth: Interventions and outcomes

Interventions included 41 studies evaluating multiple component investigation protocols (e.g. at least two of review of the medical history, postmortem pathological examination, placental examination, postmortem imaging, laboratory blood testing for mother or baby). Outcomes were most frequently reported in the investigation domain (127 outcomes). The six most frequently reported outcomes were identification of cause of death, reported in 41% (47 of 116 studies), proportion consenting to postmortem, reported by 16% (18 of 116 studies), uptake of postmortem, reported by 12% (14 of 116 studies), identification of fetal congenital abnormality, reported by 10% (11 of 116 studies), identification of a placental cause of death and identification of acquired or inherited thrombophilia, reported by 6% (7 of 116 studies). Only one study measured parents' experience of an intervention to understand why a baby died and only one study reported on parents' perceived understanding of the cause of their baby's death.

3.4 | Psychosocial support: Interventions and outcomes

Psychosocial support interventions evaluated included bereavement support interventions (5 studies), cognitive behavioural therapy (4 studies), counselling (4 studies) and yoga (3 studies). Outcomes were most frequently reported in the mental health domain (10 outcomes). The most commonly reported outcomes were experience of intervention/care, reported by 43% (12 of 28 studies), depression, reported by 29% studies (8 of 28 studies), grief, reported by 29% studies (8 of 28), PTSD, reported in 25% of studies (7 of 28 studies), and anxiety, reported in 14% (4 of 28 studies). Only two studies within this category reported on relationship outcomes and no studies assessed the effect of a psychosocial intervention on existing children or family.

3.5 | Multiple pregnancy: Interventions and outcomes

Only two interventions and two studies were included in this category. One study assessed the impact of intrauterine rescue transfusion and the other on bereavement care for a stillbirth in a multiple pregnancy. The study related to intrauterine rescue transfusion reported solely on medical outcomes related to the surviving twin, e.g. abnormalities on cranial ultrasound, fetal acidaemia or neurodevelopment outcome of the surviving twin. No psychosocial, experiential or grief outcomes were reported.

TABLE 3 Summary table of outcomes and domains from systematic review.

Domain	Definition	No. of outcomes	No. of studies
Labour & Birth	Medical outcomes related labour and birth, for example, time from induction to birth, adverse events or complications during birth, mode of birth, use of analgesia	52	55
Postpartum	Medical outcomes immediately following birth and up to 6 weeks afterwards, postpartum complications, for example, postpartum haemorrhage, retained placenta	38	32
Delivery of care	Care related outcomes, for example, experience of satisfaction with care or healthcare professionals, support from healthcare professionals, adherence to intervention, hospital use outcomes, length of hospital stay following diagnosis of stillbirth	29	45
Investigations	Outcomes related to the investigation of stillbirth, for example, identification of cause of death or medical diagnosis following investigation, proportion consenting to postmortem or investigations	127	120
Multiple pregnancy outcomes	Outcomes specifically related to cases where a stillbirth occurs in a multiple pregnancy, for example, clinical outcomes of surviving twin, attachment to survivor	8	2
Mental health	Outcomes related to mental health, for example, depression, anxiety, post-traumatic stress disorder	18	35
Emotional functioning	Outcomes related to emotional health, for example, emotional regulation, feelings, self-compassion	27	20
Grief and bereavement outcomes	Outcomes related to grief and bereavement, for example, grief, complicated grief, coping with grief	9	22
Social functioning	Outcomes related to social functioning, for example, social support, support from family, friends, social role impairment	6	6
Relationship outcomes	Outcomes related to relationships with partner, friends, family, for example, relationship difficulties, quality	6	6
Whole person outcomes	Outcomes related to physical functioning, for example, poor physical health, physical mobility, health-related quality of life, outcomes affecting the whole body and not attributed to a particular system, self-reported health, sleep	7	7
Subsequent pregnancy	Outcomes related to a subsequent pregnancy after stillbirth, for example, live birth, complications in pregnancy, preterm birth, pregnancy anxiety	47	12
Subsequent children and siblings	Outcomes related to subsequent children and siblings after stillbirth, for example, attachment to infant, parental concerns	2	2
Economic	Outcomes related to the financial cost of stillbirth intervention or care, for example, costs of hospital care and treatment	15	5

3.6 | Care in subsequent pregnancy: Interventions and outcomes

Interventions in this category primarily focused on the medical treatment of women in a subsequent pregnancy, including six studies on thromboprophylaxis in a subsequent pregnancy. Only three studies evaluated care and one study reported on psychological support interventions in a subsequent pregnancy. The most frequently reported outcomes were live birth in a subsequent pregnancy, reported in 29% of studies (4 of 14 studies), complications during a subsequent pregnancy, reported in 21% (3 of 14 studies), birthweight in a subsequent pregnancy, reported in 21% (3 of 14 studies), and anxiety, reported in 21% (3 of 14 studies). Only two studies reported on experience of care and one study on prenatal attachment in a subsequent pregnancy. No studies reported on the frequency of post-traumatic stress disorder (PTSD) or grief in a subsequent pregnancy.

3.7 | Outcome measurement

Table S5 lists all outcomes, their definitions and measurement instruments used (if applicable). There was variation in the definition of reported outcomes (range of definitions 0–35). For example, for postpartum complications there were five different definitions. No definition was provided for 247 outcomes. In all, 242 outcome measurement tools were identified. There was variation in the type of outcome measurement tools used to measure the same outcomes, with a range

of 0–22 tools used for a single outcome. Outcomes were measured at different timepoints relative to the stillbirth and were dependent on the type of intervention (Appendix S4). A total of 190 outcomes were measured during labour and birth, 76 outcomes in the postpartum period (up to 6 weeks postpartum), 246 outcomes following investigations, 66 outcomes within the first year, 101 outcomes in the first 5 years and 24 at 5 years or more.

4 | DISCUSSION AND CONCLUSION

4.1 | Main findings

The objective of this systematic review was to generate a comprehensive long-list of outcomes to inform the development of a core outcome set for stillbirth care research; in all, we identified 391 unique outcomes. We demonstrated the wide variation of interventions implemented and assessed, and outcomes reported. Where studies reported the same outcome, there was considerable variation in the reporting of the outcome definition and measurement tool used. Outcomes were measured at different timepoints relative to the stillbirth, with few studies measuring long-term outcomes, i.e. within the first year or beyond 5 years.

We identified a diverse range of interventions after stillbirth. However, there is a paucity of evidence on a number of specific types of intervention, for example, counselling, specific psychological therapy or targeted interventions in a subsequent pregnancy. Interventions after stillbirth address different aspects of care, including medical, psychological, social and long-term health. We found that the majority of studies did not measure the effect of interventions or care on parents, perceived experience, grief or psychosocial outcomes.

4.2 | Strengths and limitations

A strength of this study is its comprehensive inclusion of both non-randomised, non-comparative and RCTs, allowing for a wide range of interventions and outcomes to be identified. Previous systematic reviews on stillbirth care have only focused on RCTs or interventions targeting physical or mental health of parents, rather than broader outcomes, e.g. social, economic or experiential outcomes.[8–10,257] Robust methods have been utilised in the review, including independent duplicate screening, double extraction and extensive reference searching. An inclusive approach was adopted and high-, middle- and low-income countries have been included in the systematic review, increasing the global relevance of the review. An international steering group, including parents with lived experience of stillbirth, have informed the scope, study design and development of the outcome domains and long-list.

A limitation is that for resource reasons, non-English language articles were excluded, which in turn may have limited the number studies identified from low- and middle-income countries. We found that very few studies have been conducted in low-income countries (which have the highest burden of stillbirth). Therefore, the outcome list generated from this review may omit outcomes most relevant to these settings. Engaging low- and middle-income countries in future core outcome set development will be vital to ensure a globally representative core outcome set is created.

Only studies published over the last 24 years were included. Older publications may describe different interventions or outcomes; however, they might not have been as relevant for informing a contemporary outcome inventory, as stillbirth bereavement care has advanced in recent times.[258] Case studies, conference abstracts, protocols and dissertations were excluded. This could have led to the omission of newer interventions and novel outcomes evaluated in research yet to be published in full manuscript form. Furthermore, this review found that only 23 studies included fathers or non-birthing partners in the assessment of their outcomes, even though the impact of stillbirth has a dyadic (couple) context for many.[259] We identified only 10 studies that included parents or members of the public in their study design. This underlines the need for a future core outcome set to incorporate the viewpoints of patients and members of the public in the selection of the most important outcomes.

4.3 | Interpretation

This systematic review highlights the wide variation in research studies relating to stillbirth care, by identifying the heterogeneity of interventions and outcomes measured and reported. The lack of standardisation and the frequent failure to report on important outcomes such as maternal mortality and psychosocial outcomes, and to assess long-term effects, in many studies hampers progress towards providing optimal care after stillbirth. The problems for stillbirth care evidence are not unique; previous systematic reviews conducted in obstetrics and gynaecology and other specialties, have found similar heterogeneity in outcome reporting, definitions and outcome measurement tools.[260–268] The outcomes identified in this systematic review have contributed to the development of an outcome long-list and are being used in an international Delphi consensus process to define a minimal core outcome set for stillbirth care research.[13]

More studies with robust methodology are needed to improve the clinical evidence for care after stillbirth. For example, there were no RCTs identified for interventions to improve hospital or follow-up bereavement care. This could be due in part to the ethical challenges of performing trials in this field, such as the perceived fear of causing harm to bereaved parents and the appropriateness of RCT methodology to evaluate psychosocial support interventions after stillbirth.[12] Studies have found bereaved parents are positive about participating in research and good recruitment rates

have been demonstrated when the approach has been guided by patient and public involvement.[225,248,269]

There appears to be several significant evidence-practice gaps into specific interventions after stillbirth. Surprisingly, no interventions were identified on lactation care (e.g. breast milk suppression or milk donation) and personalisation of care at any stage. Several interventions related to subsequent pregnancy have not been studied, including continuity of care, pre-pregnancy counselling, targeted antenatal interventions for women with modifiable risk factors (e.g. diabetes or smoking) and additional antepartum ultrasound surveillance.[12] Moreover, no interventions were identified to support parents from minority ethnic and socio-economic backgrounds following stillbirth, which could be intensifying health inequalities.[270] Interestingly, we identified no studies on interventions to support the LBTQ+ (lesbian, gay, bisexual, transgender, queer/questioning, asexual and others) community. Future research should focus on an exploration of potential interventions in these contexts and populations.

5 | CONCLUSION

This systematic review has highlighted the large variation in outcomes assessed, and outcome definitions and outcome measurement instruments used. These inconsistencies limit the utility of primary research and of evidence synthesis, and impact adversely on quality of decision making in the field of stillbirth aftercare. Considerable research gaps on specific intervention types in stillbirth care were also identified. The findings of this systematic review strongly support the need to develop a core outcome set for stillbirth care research.

AUTHOR CONTRIBUTIONS

Study concept: DB, CB, AF, AD, DS, LH, JMND. Study design: DB, CB, AF, AD, DS, LH, JMND, AM, KB & iCHOOSE Collaborative Group. Drafting of the article: DB. Development of search strategy and electronic searches of the medical literature databases: DB & KB. Screening of titles, abstracts and full texts: DB, AM, AD, CS, KB. Data extraction: DB, AM, AD, CS, KD, KB, ES, AL, CB. Data analysis: DB, AD, CB & AF. Critical revision of the article for important intellectual content and approval of final paper: DB, CB, AF, AD, DS, LH, JMND, AM, KB, ES, CS, KD, AL & iCHOOSE collaborative group. Study supervision: CB, AF, DS, LH & AD.

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CONFLICT OF INTEREST STATEMENT

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DATA AVAILABILITY STATEMENT

Data sharing not applicable as no new data generated.

ETHICS APPROVAL

None required.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX 1

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