NIHR | Innovation Observatory

Newcastle University

NIHR Women's Health Challenge: Supporting prioritisation through intelligence synthesis

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Executive summary

- Inequalities in women's experiences of maternity services and their outcomes have been documented by several recent reports, including those published by the Care Quality Commission in England.
- To understand more about whether upcoming or ongoing research may be addressing these concerns, and to support the prioritisation process for the NIHR's Maternity Inequalities Challenge, we undertook two horizon scans to look for clinical trial registrations and funding records surrounding maternity services in the UK since 2020.
- We found 31 clinical trial registrations and 34 funding records either entirely or partly set within the UK that met our eligibility criteria.
- Most of these focused on interventions that take place during the antenatal period and around half of all included records were for randomised controlled trials (RCTs).
- Only 12 of 31 clinical trial registrations and 13 of 34 funding records listed a patient-reported outcome measure as part of the study.
- Only 5 of 31 clinical trial registrations and 1 of 34 funding records listed a patient-reported experience measure as part of the study.
- We found little evidence of either clinical trial registrations or funding records mentioning ways in which demographic variables that can contribute to health inequalities were being considered or addressed.
- Only 2 of 31 clinical trial registrations and 5 of 34 funding records considered the potential impact of the PROGRESS-Plus domain race, ethnicity, culture or language.
- Future research surrounding maternity services in the UK should aim to include patient-reported outcome measures and patient-reported experience measures, as well as state how different demographic variables that may contribute to health inequalities will be considered.

Background

Maternity services in England cover care in the pathway from conception and pregnancy (antenatal care) to birth and postnatal care. Antenatal care includes but is not limited to: pregnancy ultrasound scans; screening tests for foetal anomalies; blood tests to check for syphilis, HIV and hepatitis B; screening for sickle cell and thalassaemia; assessments for gestational diabetes, pre-eclampsia and hypertension; identification of breech presentations; and the offer of antenatal classes, such as breastfeeding workshops.[1,2] Perinatal (birth) care encompasses labour and delivery, including induction of labour, support during labour and surgical or assisted delivery. Postnatal care for women includes: assessment of general health and wellbeing after birth, including psychological and emotional wellbeing; and assessment of postpartum vaginal bleeding and perineal health.[3]

The Care Quality Commission's (CQC) maternity survey 2023 examined the experiences of women and other people who had a live birth in early 2023 and noted that people's experiences of maternity care have deteriorated over the past five years.[4] The overall quality of maternity services has also been highlighted in the CQC's State of Care 2022-23 report, as 10% of maternity services were rated as inadequate overall and 39% as requiring improvement, with safety and leadership remaining areas of concern.[5]

Specific inequalities in women's experiences have also been highlighted by recent reports. The CQC have highlighted that women from minority ethnic groups continue to be at higher risk when using maternity services,[5] while women with long-term mental health conditions were also more likely to report poorer experiences.[4] The Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK) report identified that the risk of maternal death between 2020 to 2022 was almost three times higher among women from black ethnic minority backgrounds compared with white women, with women from Asian backgrounds also being at higher risk of mortality than white women.[6]

To tackle such inequalities, as well as to reduce pressures on secondary care and waiting lists and to improve outcomes for women across the life course, Women's Health Hubs have been introduced as a new model of care within the community.[7]

In January 2024, the Department for Health and Social Care announced its new women's health priorities; these include menstrual problems and menopause, maternity care and birth trauma support.[8] Specifically, the priorities include the aim to bolster maternity care before, during and after pregnancy, with £50m to be dedicated to the first ever National Institute for Health and Care Excellence (NIHR) "challenge".[8] The challenge will see researchers, policymakers and women collaborating to find new ways to tackle disparities within maternity care.

To support the establishment of the NIHR's challenge and prioritising of potential research topic areas, the NIHR Innovation Observatory produced two horizon scans to identify: (i) ongoing clinical trials; and (ii) research funding within maternity services.

Aim

The aim of this work was to provide intelligence to the NIHR's Women's Health Challenge Consortium by conducting two separate scans.

The key objectives were:

- to provide a clinical trial scan of the current landscape within the space of maternity services (including antenatal care, obstetrics, and postnatal care); and
- to provide a funding scan depicting the current landscape of research funding within maternity services (including antenatal care, obstetrics, and postnatal care).

Methods

Search strategies

A comprehensive list of keywords and concepts were compiled by the Innovation Observatory's Information Specialist (CE) and refined through scoping searches, testing and evaluation of relevance.

We searched ClinicalTrials.gov and WHO International Clinical Trials Registry Platform (ICTRP) on 13 March 2024 for clinical trial registrations. We excluded any registrations prior to 2020 from the searches to help ensure that trials and their potential results were more current. Recruiting status in ClinicalTrials.gov was restricted to 'not yet recruiting', 'active', 'not recruiting', and 'completed'; no limits to recruitment status were employed in the WHO ICTRP search. Search results were then combined and deduplicated. The full search strategies can be found in Appendix A.

The funding source searches were carried out in NIHR Funding and Awards, UK Research and Innovation Gateway (UKRI GtR), and 360 Giving on 18 March 2024, and Europe PMC on 19 March 2024. These searches used condensed search strings from the comprehensive list after testing for relevance on key terms and were restricted to 'start year' or 'award date' from 2020. Deduplication was carried out within each funding source set of results. The full search strategies can be found in Appendix B.

Eligibility criteria

The full eligibility criteria for the clinical trials scan are outlined in Table 1.

Table 1: Eligibility criteria for clinical trial scan

PICO element	Included	Excluded
Study design	• Trial registrations for randomised controlled trials (RCTs, including parallel, cross-over and cluster-RCTs) • Trial registrations for CCTs • Trial registrations for observational studies (cohort studies)	• Protocols for implementation studies • Protocols for process evaluations • Protocols for case-control studies • Protocols for cross-sectional studies • Case reports and case series • Systematic reviews/ other forms of evidence synthesis • Protocols for qualitative studies

PICO element	Included	Excluded
Population	• Women or pregnant people of any age using maternity services – both antenatal and postnatal, not limited by any subgroup (e.g. age, comorbidities, any PROGRESS-Plus related characteristic) • Postnatal period is considered 6-8 weeks after birth, as per standard guidelines • Healthcare professionals (HCPs) working in maternity services where the intervention is targeted at HCPs to improve services or practice • Any setting (e.g. home, community, outpatient, maternity ward, birth centre)	• Studies focusing on gynaecological conditions (e.g. endometriosis, polycystic ovary syndrome) • Studies focusing on gynaecological cancer (e.g. ovarian cancer, cervical cancer) • Studies focusing on neonates and babies after birth rather than targeting the mother, birthing person or HCPs caring for the mother or birthing person

Intervention	• Interventions to improve maternity services for example (but not limited to)
	  • Novel training courses for HCPs
	  • Telehealth within maternity services
	  • Different models of care (e.g. continuity care)
	  • Educational interventions
	  • Differing timing of first health visitor visit postpartum
	  • Differing lengths of postpartum stay
	  • Care for women experiencing baby loss or premature birth
	  • Interventions for increasing breastfeeding
	• Interventions targeted at both parents (e.g. couples' counselling, parental education schemes)
	• Interventions for miscarriage or baby loss, up to 8 weeks after baby loss
	• Genetic/foetal testing during the antenatal period
		• Interventions for gynaecological conditions (e.g. endometriosis, PCOS)
		• Interventions for gynaecological cancers
		• Interventions for HCPs in maternity care where the intervention does not specifically focus on improving care or services
		• Pre-conception care (e.g. wellbeing programmes for improving chances of being pregnant, IVF)
		• Interventions focusing on neonates and babies after birth rather than targeting the mother or HCPs caring for the mother (e.g. kangaroo care)
		• Interventions targeted only at fathers with no outcome or involvement for the mother

PICO element	Included	Excluded
Outcomes	• Any measure of physical health • Any measure of mental health • Any adverse events • Any laboratory outcome (e.g. blood tests) • Any birth outcome (e.g. need for caesarean section, pre-eclampsia, pre-term birth) • Any measure of service improvement (e.g. reduced waiting times) • Any feasibility outcome (e.g. feasibility of randomising participants in a future RCT)	• Any study not reporting at least one eligible outcome measure
Other limitations	• Registered in or after 2020 • Published in English • UK– either entirely set in the UK or at least one recruiting centre is within the UK	• Protocols or trial registrations where results have already been published • Not published in English • Registered before 2020 • Not set within the UK or does not have at least one participating centre in the UK • Location of trial not reported
Abbreviations: CCT = clinical controlled trial; HCP = healthcare professional; IVF = in-vitro fertilisation; PCOS = polycystic ovary syndrome; RCT = randomised controlled trial; UK = United Kingdom		

The eligibility criteria for the funding scan are detailed in Table 2.

Table 2: Eligibility criteria for funding scan

Domain	Included	Excluded
Design	• Clinical trials/RCTs, including feasibility or pilot RCTs • CCTs • Cohort studies • Any programme of work where at least one work package includes one of the above	• Cross-sectional studies alone* • Qualitative studies alone* • Systematic reviews, qualitative evidence syntheses or realist reviews* • Implementation science* • Process evaluations (e.g. linked to HTAs)*
Location	• UK– either entirely set in the UK or at least one location is within the UK	• Any other country not including the UK
Purpose	• Determine or observe the effectiveness of interventions within maternity	• Funding to facilitate activities other than research studies (e.g. for setting up a maternity

Domain	Included	Excluded
	services/obstetrics (e.g. through clinical trials) • At least one outcome measure targets the mother or birthing person	group, supporting the running of a charity)* • Design or non-clinical assessment of an intervention* • Proof of concept* • Implementation science* • All outcome measures target neonates, infants, or only fathers
Other limits	• Published in English • Funding start date is during or after 2020	• Not published in English • Funding start date is before 2020
* NB: unless these are part of a work package or programme of work that includes an eligible study design **Abbreviations**: CCT = controlled clinical trial; HTA = Health Technology Assessment; RCT = randomised controlled trial; UK = United Kingdom		

Screening

Results from the clinical trial searches were deduplicated using EndNote and imported into Rayyan for screening against the eligibility criteria.[9] One reviewer (EEJ) screened all clinical trial records for eligibility, with two reviewers (BH and AJ) checking 10% of the library each for accuracy. As reviewer agreement was high, single screening of the remaining 80% of records was deemed appropriate. Any disagreements were resolved by discussion.

Results from the funding scan searches were imported into Microsoft Excel spreadsheets for screening. Ten percent of each of the libraries were first screened by two reviewers independently (EEJ and either BH or AJ) to ensure accuracy against the eligibility criteria. Any disagreements were resolved by discussion or, if required, via arbitration by a third reviewer (GN). Once resolved and any ambiguities in the eligibility criteria discussed, the remaining records were either screened by a single reviewer (of EEJ, BH or AJ) or by two independent reviewers (EEJ and BH) in cases where reviewer agreement at the pilot stage was deemed lower. For records that were single screened at this stage, any records with unclear eligibility were marked and a second reviewer determined whether the record was eligible for inclusion. Any further disagreements were resolved by discussion or, if required, via arbitration by a third reviewer (GN).

Data extraction

We created two data extractions forms in Microsoft Excel; one for the clinical trials scan and one for the funding scan. Two reviewers (EEJ and BH) piloted each data extraction form on 10% of the included clinical trials and funding calls before discussing any disagreements and potential refinements to the form.

For the clinical trials scan, following piloting and refinement, one reviewer (EEJ) extracted the remaining clinical trial registrations, which were then checked by another reviewer for accuracy (BH). For the funding scan, the remaining included records were extracted by one of two reviewers (either EEJ or BH). For both scans, any disagreements were resolved by discussion.

The final extraction form for the clinical trials scan contained the data items outlined in Table 3.

Table 3: Data items extracted for the clinical trial scan

Domain	Specific items
Bibliographic details	• Trial identifier (e.g. NCT number) • Official title • Trial status (recruiting, active not recruiting, completed) • Year first posted/registered • Sponsor (government, charity, industry, other) • URL
Design	• Study design (RCT/observational) • UK only (Y/N) • Study site locations (only UK sites extracted) • Service type (antenatal, perinatal, postnatal, or a combination of these) • Intervention • Intervention type (medicines, diagnostic, risk prediction, monitoring, education, model of care, other) • Comparator (where applicable)
Outcome measures	• Any measure of physical health • Any measure of mental health • Any adverse events • Any laboratory outcome (e.g. blood tests) • Any birth outcome (e.g. need for caesarean section, pre-eclampsia, pre-term birth) • Any measure of service improvement (e.g. reduced waiting times) • Any feasibility outcome (e.g. feasibility of randomising participants in a future RCT) • Whether patient-reported outcome measures (PROMs) are reported (yes/no) • Whether patient-reported experience measures (PREMs) are reported (yes/no)
Subgroups	• Population (general or targeted, with description of targeted population where appropriate) • Subgroups included (Y/N)
PROGRESS-Plus criteria[10,11]	• Place of residence • Race/ethnicity/culture/language • Occupation • Gender/sex • Religion • Education • Socioeconomic status • Social capital • Personal characteristics (e.g. age, disability) • Features of relationship (e.g. smoking parents, excluded from school) • Time-dependent relationships (e.g. leaving hospital, respite care, other instances where a person may be temporarily at a disadvantage)

Domain	Specific items
Abbreviations: N = no; PREM = patient-reported experience measure; PROM = patient-reported outcome measure; RCT = randomised controlled trial; UK = United Kingdom; URL = uniform resource locator; Y = yes	

The final extraction form for the funding scan contained the data items outlined in Table 4.

Table 4: Data items extracted for the funding scan

Domain	Specific items
Bibliographic details	• Title • URL • Funder name (e.g. NIHR) • Type of funder (governmental, charity, industry, other) • Funding call title • Total awarded • Funding aim
Design	• Study design (RCT, observational study) • Whether the eligible study design was nested within a programme of work packages (yes or no) • Service type (antenatal, perinatal, postnatal, or a combination of these) • Intervention • Intervention type (medicines, diagnostic, risk prediction, monitoring, education, model of care, other) • Comparator (where applicable)
Outcome measures	• Any measure of physical health • Any measure of mental health • Any adverse events • Any laboratory outcome (e.g. blood tests) • Any birth outcome (e.g. need for caesarean section, pre-eclampsia, pre-term birth) • Any measure of service improvement (e.g. reduced waiting times) • Any feasibility outcome (e.g. feasibility of randomising participants in a future RCT) • Whether patient-reported outcome measures (PROMs) are reported (yes/no) • Whether patient-reported experience measures (PREMs) are reported (yes/no) • Whether patient and public involvement and engagement (PPIE) is described
Subgroups	• Population (general or targeted, with description of targeted population where appropriate)
PROGRESS-Plus criteria[10,11]	• Place of residence • Race/ethnicity/culture/language • Occupation • Gender/sex • Religion • Education • Socioeconomic status • Social capital • Personal characteristics (e.g. age, disability)

Domain	Specific items
	• Features of relationship (e.g. smoking parents, excluded from school) • Time-dependent relationships (e.g. leaving hospital, respite care, other instances where a person may be temporarily at a disadvantage)
Abbreviations: N = no; NIHR = National Institute for Health and Care Research; PPIE = patient and public involvement and engagement; PREM = patient-reported experience measure; PROM = patient-reported outcome measure; RCT = randomised controlled trial; UK = United Kingdom; URL = uniform resource locator; Y = yes	

For these scans, we classed the service type (antenatal, perinatal, postnatal or a combination of these) based on the period when an intervention is planned to be delivered or the observational period will take place.

Where full protocols were available on the clinical trial registration or funding record, we read these to supplement information provided by the trial registration details, abstracts and plain language summaries.

Data synthesis

We tabulated and narratively synthesised data for both the clinical trial scan and funding scan using a modified version of the principles of Synthesis Without Meta-Analysis (SWiM).[12] First, we grouped included clinical trials and funding reports by study design (RCT/CCT or observational), service type (antenatal, perinatal, postnatal, or a combination of these) or both, where possible. We also stratified reporting of outcome measures by the service type targeted. Furthermore, we investigated any similarities or heterogeneity in types of outcomes assessed and PROGRESS-Plus domains reported, narratively describing any gaps.

Synthesis included graphically presenting the data using graphics and charts, which we produced using the online software Flourish.[13]

Results

Results from the searches

For the clinical trials scan, we retrieved 3342 records from the searches and 519 duplicate records were removed. In total, we included 31 trial registrations and 34 funding records meeting the eligibility criteria. The PRISMA flow diagram for the clinical trial scan can be found in Figure 1 and the PRISMA diagram for the funding scan in Figure 2.[14]

Figure 1: PRISMA diagram for clinical trial scan

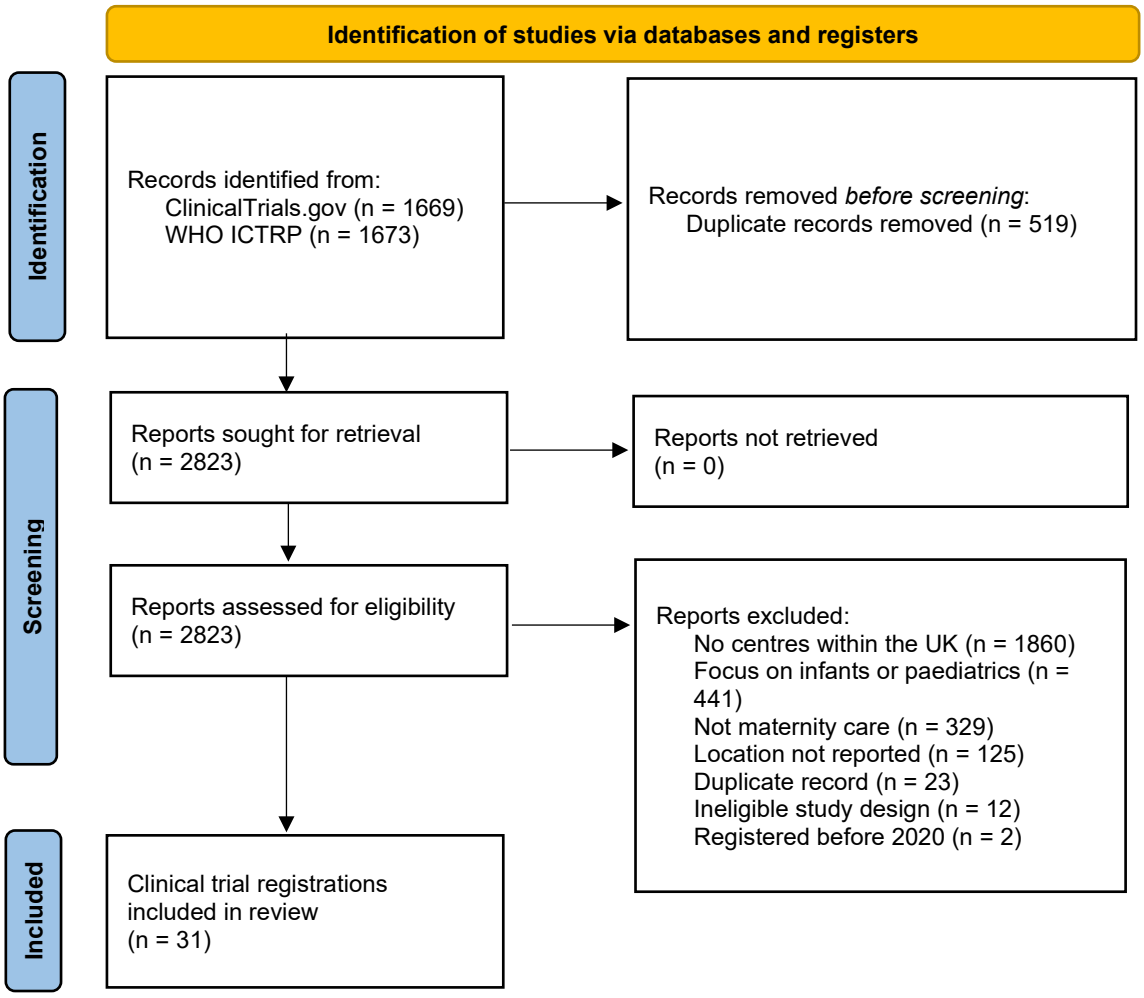
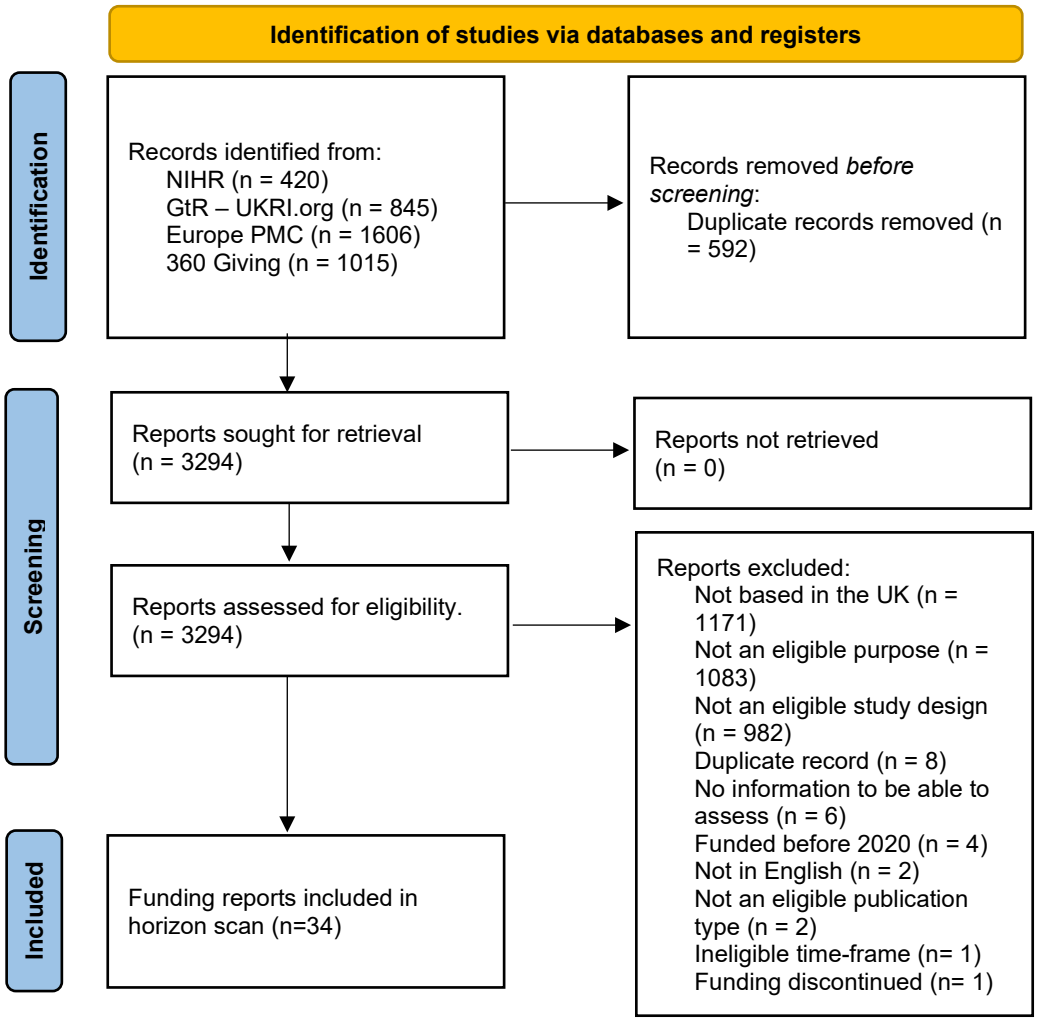


Figure 2: PRISMA diagram for the funding scan



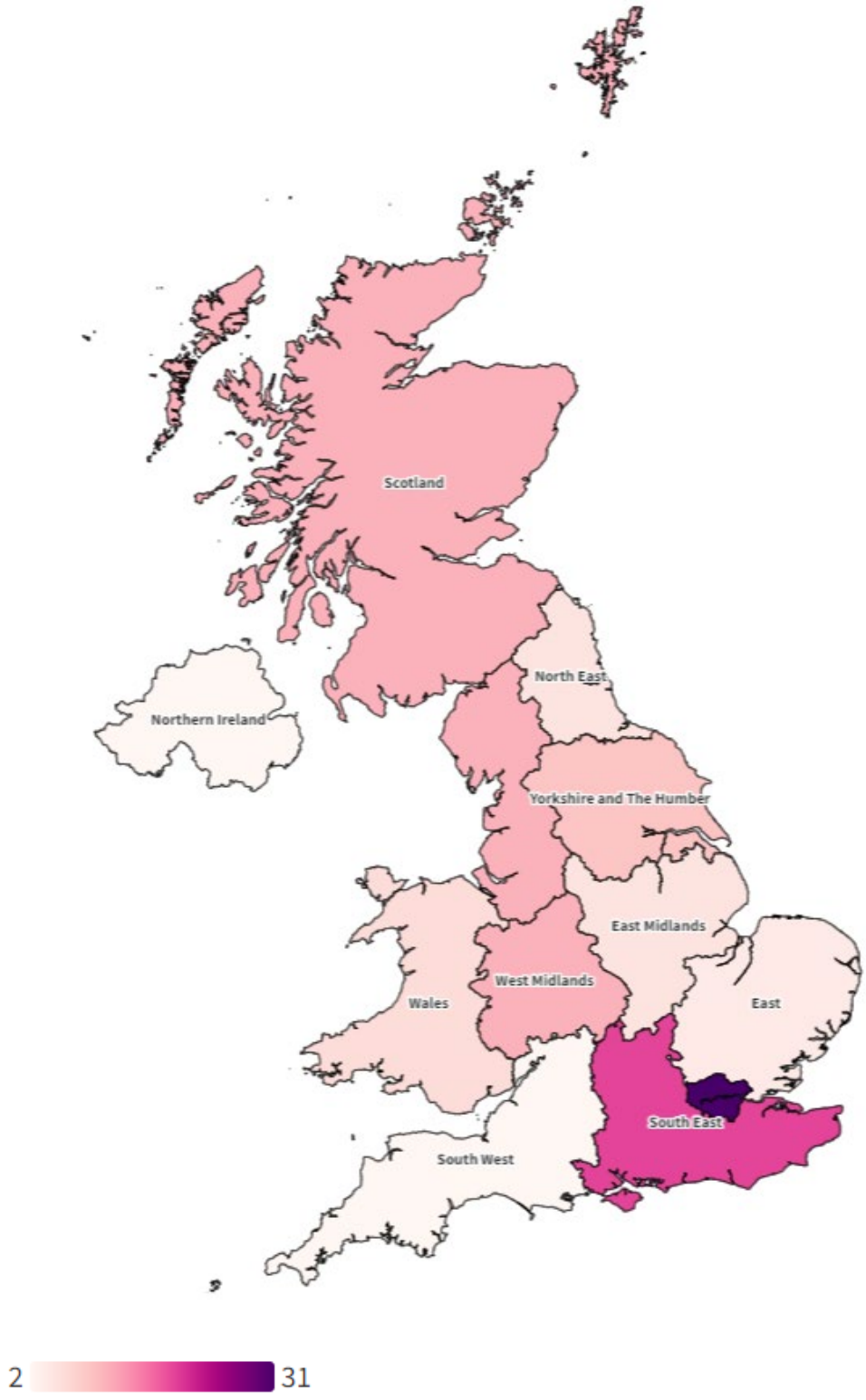
Results

Summarised characteristics of the included clinical trial registrations and funding can be found in Appendix C.

Geographical location

Of the 31 clinical trial registrations included, 26 were based solely in the UK. In total across all included clinical trial registrations, 115 centres were participating across the UK. The largest proportion of these centres were based in London (n=30), followed by the South East (n=19), Scotland (n=11) and the West Midlands (n=11). The South West (n=2), Northern Ireland (n=2) and the East of England (n=4) had the fewest participating centres.

Figure 3: Heat map of numbers of centres participating in included clinical trials by UK region



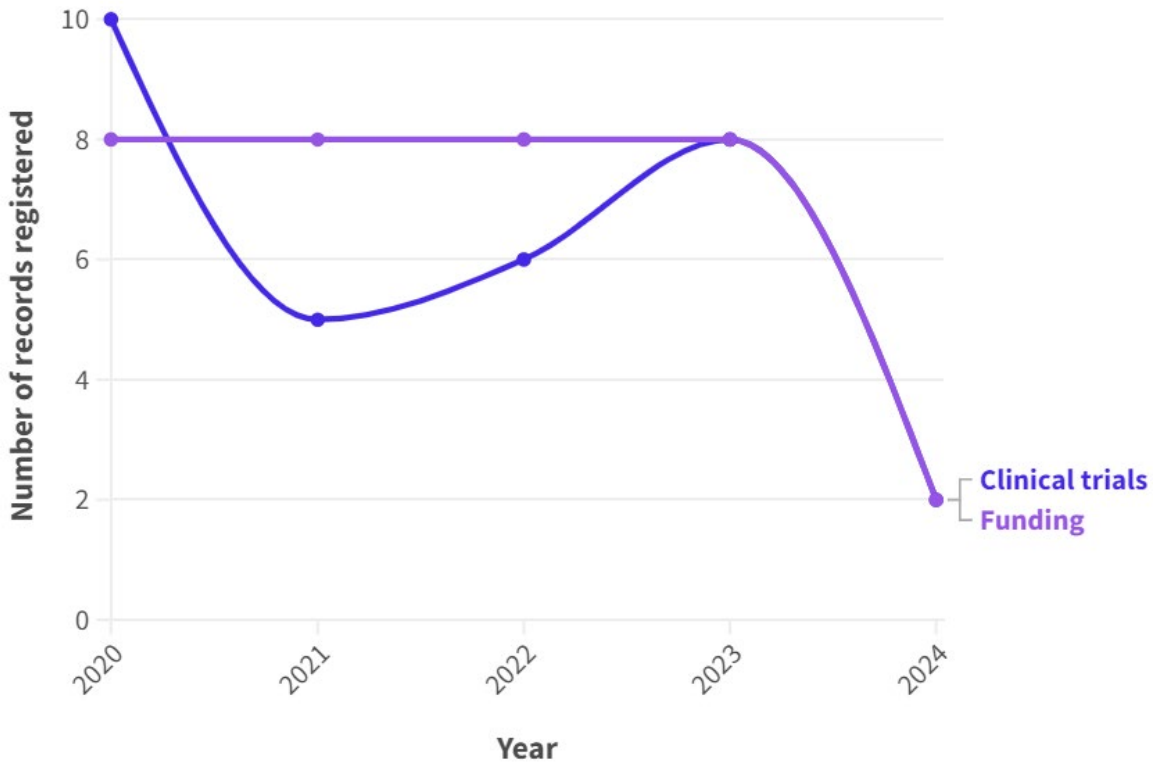
Amount of funding

One funding record did not report on the amount it had been awarded. Across the remaining 33 funding awards, £35,514,321.45 had been awarded.

Year of registration

New funding relating to trials for antenatal, perinatal and postnatal care have been steady at eight per year since 2020 and two in 2024 (as of April 2024). Clinical trial registrations with a start date in 2021 and 2022 decreased from 2020, though this may be due to the impact of COVID-19. Clinical trial registrations increased to eight in 2023 and there have been two registrations up to April 2024.

Figure 4: Number of clinical trials and funding records registered per year since 2020

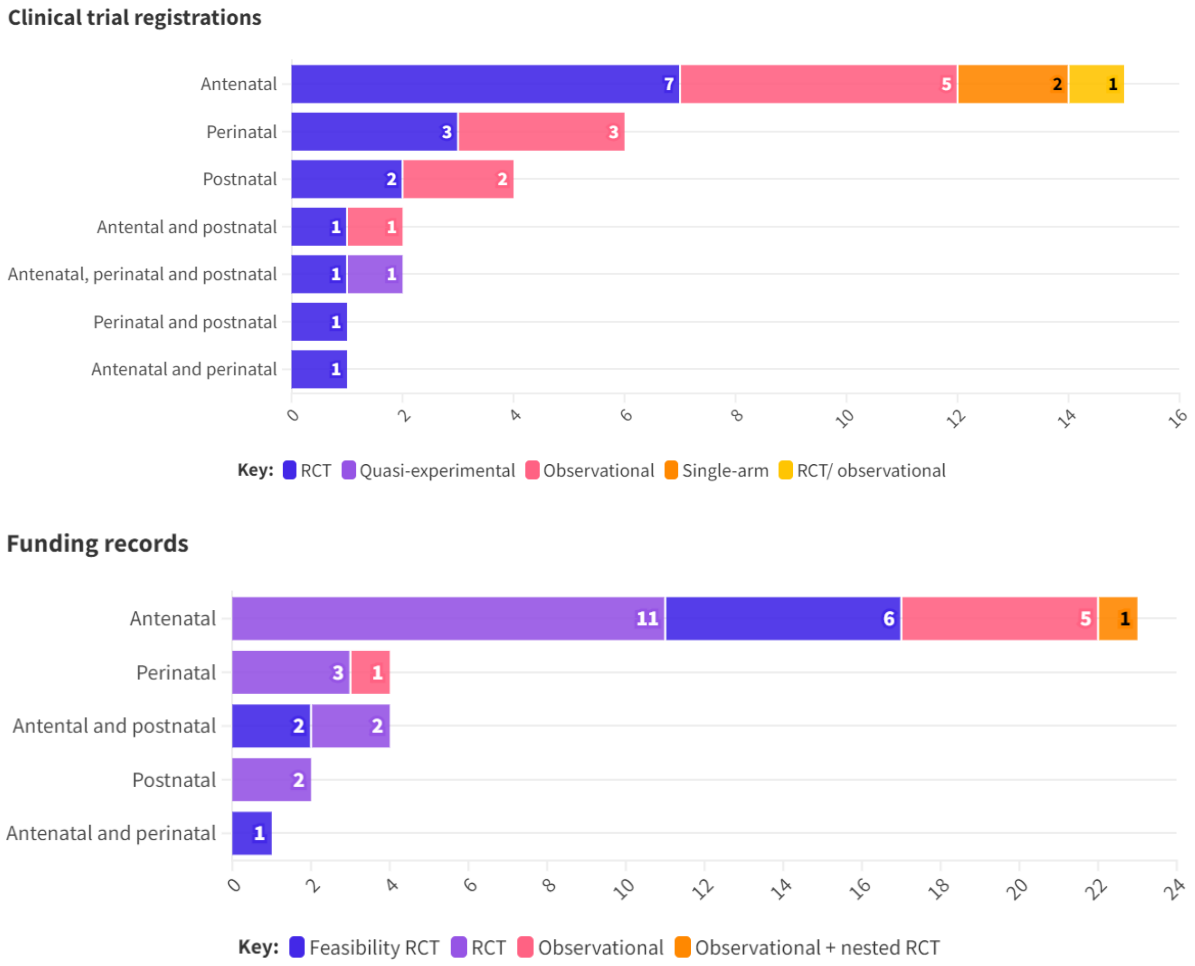


Study design

Most trial registrations were for RCTs (n=16; 50%), while 11 (35%) were observational. Two studies were single-arm intervention trials, one was quasi-experimental and one was a combination of an RCT and non-randomised study. For the funding records, 18 were RCTs (53%), nine were feasibility RCTs (26%), six were observational (18%) and one was an observational study with a nested RCT (3%).

Almost half of the clinical trial registrations solely focused on interventions delivered within the antenatal period (n=15; 47%), while most of the funding records were centred on this period (n=23; 68%). Six clinical trial records (19%) and four (12%) funding records focus on interventions in the perinatal period, with four (13%) clinical trial records and four (12%) funding records in the postnatal period. The remaining trial registrations (n=6; 19%) and funding records (n=5; 15%) aimed to assess interventions delivered at multiple stages of the maternity pathway.

Figure 5: Distribution of maternity service across study designs in included trial registrations (top) and funding records (bottom)



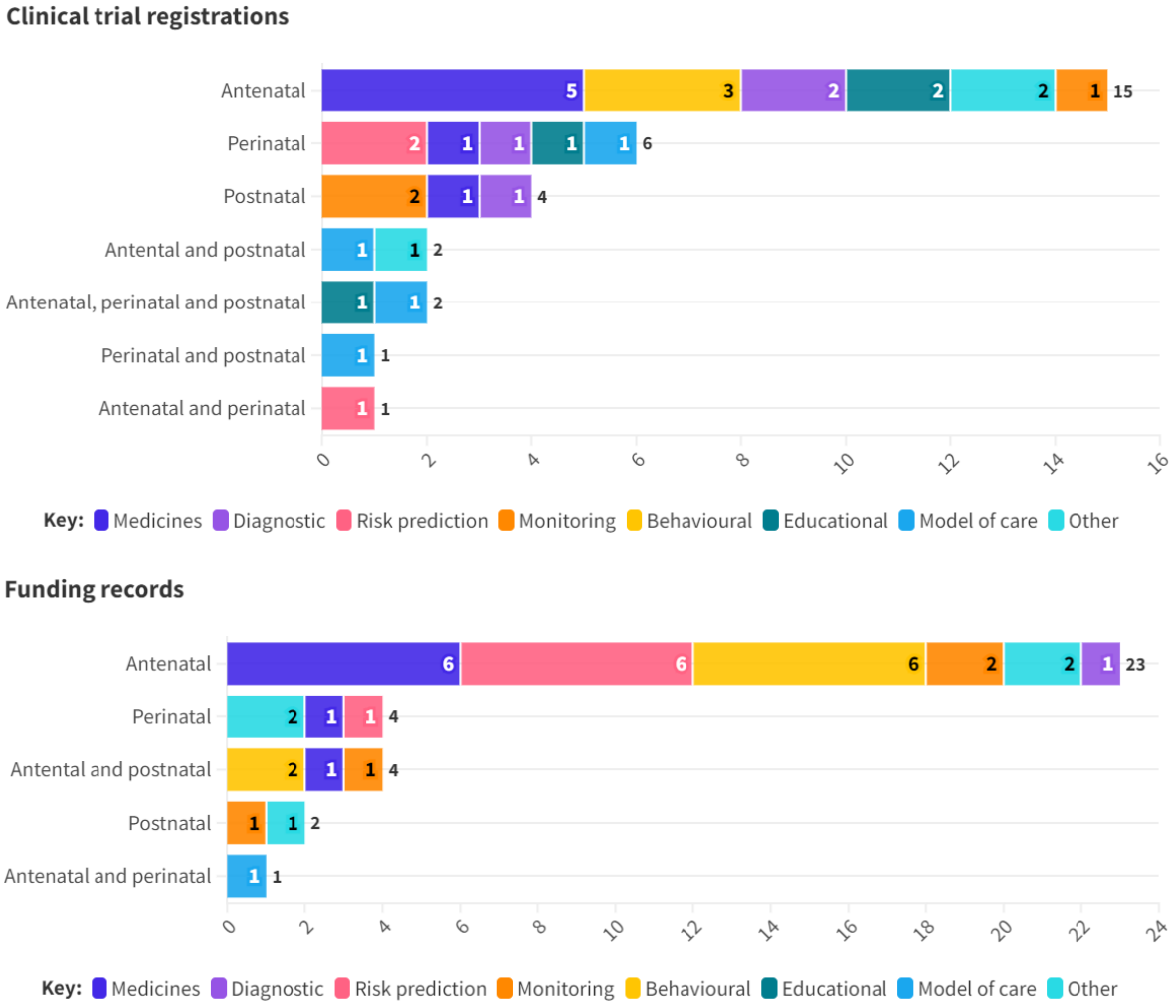
Abbreviations: RCT: randomised controlled trial

Interventions

For included trial registrations, the most frequent intervention category was medicines (n=7; 23%), while for the funding records, eight (24%) assessed medicines and another eight (24%) assessed behavioural interventions. Behavioural interventions were reported by three (10%) clinical trial registrations. Diagnostic interventions were reported by one funding record (3%) and four clinical trial registrations (13%). Educational interventions were reported in four clinical trial registrations (13%) but no funding records. Models of care were assessed by four clinical trial registrations (13%) and one funding record (3%). Risk prediction interventions were reported in three (10%) clinical trial registrations and seven (21%) funding records. Monitoring was reported in three clinical trial registrations (10%) and four funding records (12%). Three clinical trial registrations (10%) and five funding records (15%) looked at other interventions not covered by the other categories.

Full details of all interventions are presented in Appendix D.

Figure 6: Intervention categories in included records stratified by place on care pathway



Targeted groups

Around half of all clinical trial records (n=15; 48%) and slightly fewer than a third of funding records (n=10; 29%) considered non-targeted interventions. Two funding records proposed to analyse both a targeted group and a wider population. The rest targeted specific populations.

Of those that reported targeting a specific population, only three clinical trial registrations (10%) and nine funding records (26%) were focused on people with long-term conditions (e.g. HIV, clinical anxiety, likely bipolar disorder, hypertension and type 2 diabetes mellitus). One clinical trial registration targeted both midwifery and obstetric clinicians and women giving birth.

The remaining registrations and records targeted short-term conditions that usually resolve following pregnancy (e.g. gestational diabetes), twin pregnancies, new parents, or specific pregnancy-related risks (e.g. pre-eclampsia or pre-term birth).

Outcome measures

Birth outcomes (such as preterm birth or caesarean delivery) was the most frequently included outcome domain, listed in 13 of the 31 trial registrations (42%), followed by mental health (n=12, 39%) and physical health outcomes (n=11, 35%). Adverse events were only listed in eight trial registrations (26%), with six of these being listed in registrations surrounding the antenatal period. The least reported outcome domain was service outcomes (n=5, 16%). In the funding records, birth outcomes were the most reported (n= 15; 44%), followed by physical health (n=12; 35%) and mental health (n=12; 35%). Adverse events were only reported in 11 of 34 records (32%). The least reported outcome domains were service outcomes and laboratory outcomes (n=5 each; 15%).

Figure 7: Outcome measures reported in clinical trial registrations

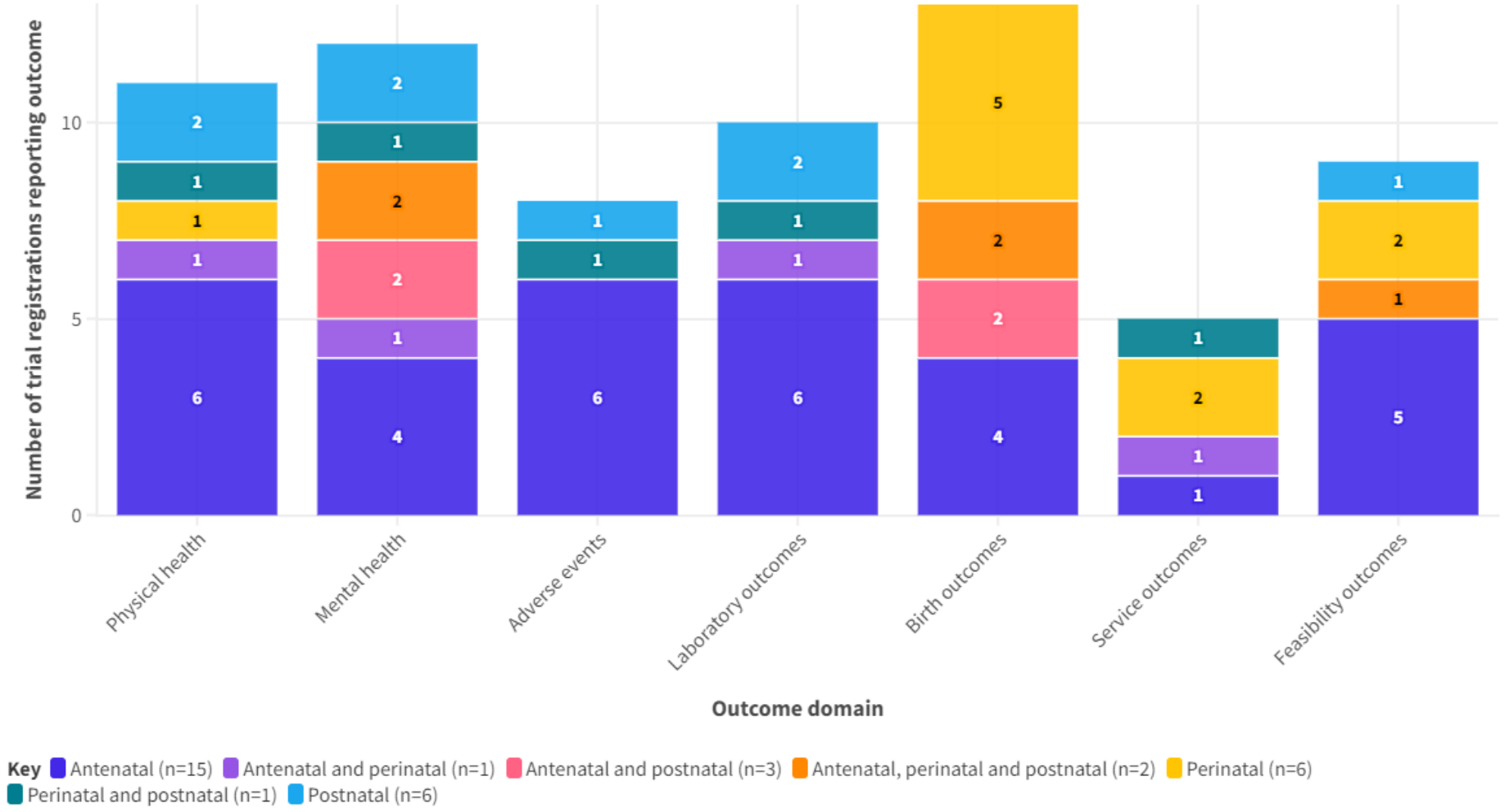
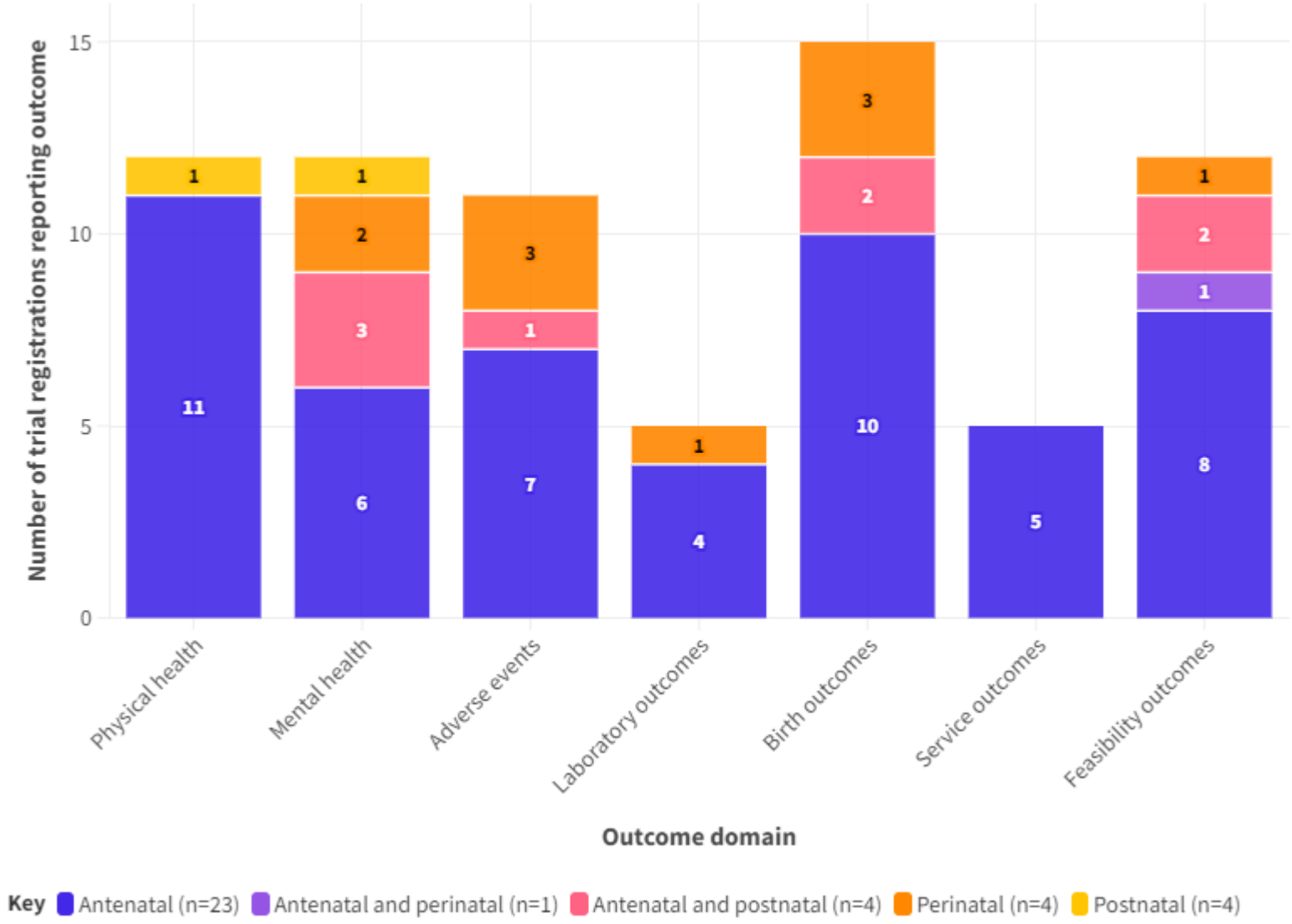
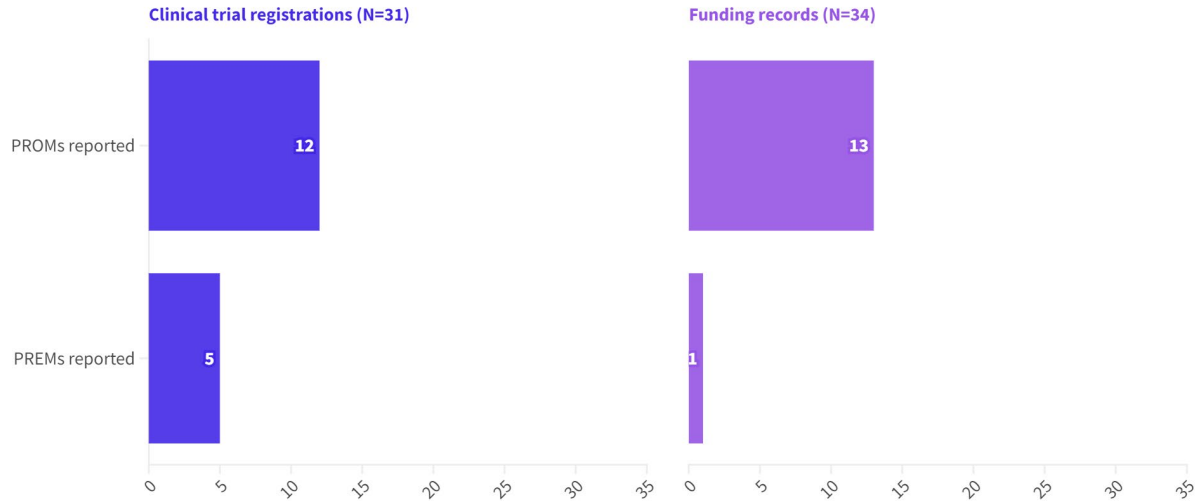


Figure 8: Outcome measures reported in funding records



Patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) were reported by fewer than half of all included clinical trial registrations and funding records. Of the clinical trial registrations, 12 (39%) included PROMs and five (16%) included PREMs, while for the funding records 13 (38%) included PROMs and only one (3%) included PREMs.

Figure 9: Summary of number of times PROMs and PREMs are reported in included clinical trial registrations and funding records

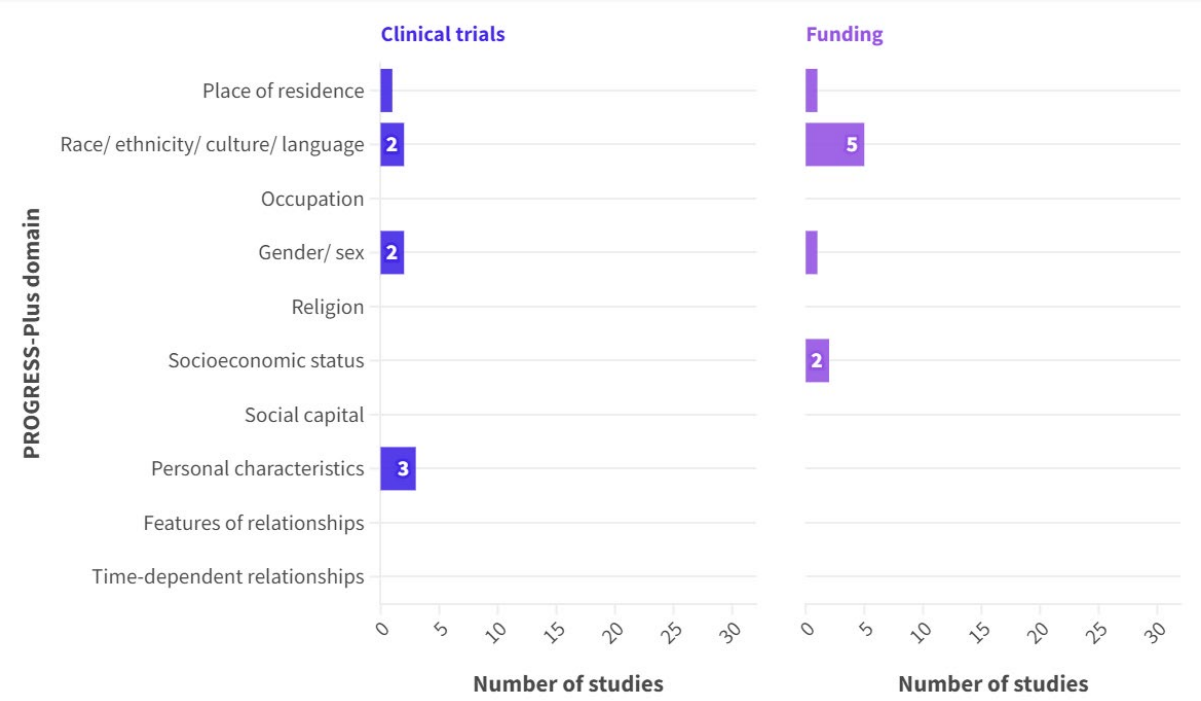


Abbreviations: PREM = patient-reported experience measure; PROM = patient-reported outcome measure

PROGRESS-Plus domains

The number of PROGRESS-Plus domains referred to or embedded as part of the inclusion criteria for the clinical trial registrations and funding records is presented in Figure 9. Place of residence was addressed by one clinical trial registration and one funding record, gender was addressed by two clinical trial registrations and one funding record, two funding records addressed socioeconomic status and three clinical trial registrations assessed personal characteristics. Two clinical trial registrations and five funding records considered race, ethnicity, culture or language. No clinical trial registrations or funding records addressed occupation, religion, social capital, features of relationships, or time-dependent relationships.

Figure 10: Number of PROGRESS-Plus domains addressed by clinical trials registrations and funding records



Patient and public involvement and engagement

We only looked for evidence of patient and public involvement and engagement in funding records. Of the 34 funding records included, 27 (79%) mentioned either how patients and the public had been involved in the work to date or how they will be involved in future work.

Discussion

Summary of results

In total, we included 31 clinical trial registrations and 34 funding records within this horizon scan. Most of the clinical trial registrations and funding records centred on interventions that take place during the antenatal period and around half of all included records were for RCTs. There were distinct gaps in reporting of PROMs, with only 12 (39%) clinical trial registrations and 13 (38%) funding records reporting a PROM. PREMs were rarely reported, with five (16%) of clinical trial registrations and one (3%) funding record listing a PREM as an outcome measure.

We found little evidence of either clinical trial registrations or funding records considering dimensions of the PROGRESS-Plus domains, with no included records addressing occupation, religion, social capital, features of relationships or time-dependent relationships. Only two clinical trial registrations and five funding records considered race, ethnicity, culture or language and only two funding records considered socioeconomic status.

However, it should be noted that, currently, clinical trial registrations and funding records tend to contain few details, with funding records normally only reporting a brief abstract or plain language summary.

Implications for further research

This report has highlighted that there still appears to be gaps in primary quantitative research either being conducted or that is planned to be conducted within maternity services in the UK, particularly in terms of how the research is attempting to address inequalities. More research is required that either targets specific groups or performs subgroup analyses to assess the effects of interventions on specific groups. This may be particularly needed for women from ethnic minority groups and those with long-term health conditions, given the CQC's findings that women from these groups are at higher risk when using maternity services.[4,5]

Furthermore, primary quantitative studies should seek to include PROMs and PREMs, particularly given that the CQC has documented a decline in people's experiences of maternity care over the past five years.[4] Core outcome sets listed in the Core Outcome Measures in Effectiveness Trials (COMET) Initiative also exist surrounding the evaluation of maternity care and preventing and treating foetal growth restriction,[15,16] while there are also ongoing core outcome sets being developed for: prelabour rupture of membranes;[17] respectful maternal and newborn care;[18] and water immersion during labour and birth.[19] Given the range of outcome domains measured by the registrations and records found in this work, using such core outcome sets, where possible, may assist in standardising the research surrounding different aspects of maternity research, enabling easier comparison and synthesis in future.

Future syntheses and horizon scans could be expanded to assess research beyond primary quantitative studies, such as qualitative studies, mixed-methods studies, intervention design and implementation science. In doing so, the findings of these horizon scans could be complemented through an assessment of the breadth of research exploring patient experiences of maternity services, as well as what innovations may be emerging that can be implemented within the field. Such syntheses and scans should include extracting information regarding the PROGRESS-Plus domains to apply an equity lens and assess whether these other study designs consider the effects of different variables that may have an impact on health inequalities.[10,11]

Strengths and limitations of this work

The major strengths of this work include its comprehensive searching across multiple international trial registries and funding sources to ensure that the chance of excluding relevant intelligence was limited. Though our approach to screening and extracting information from records may not be considered "gold standard" (i.e. these steps were not undertaken entirely by two independent reviewers), our approach aligns with the guidance from the Cochrane Rapid Reviews Methods Group recommendations in that we: conducted dual, independent screening of records and assessed reviewer agreement before assessing whether to continue with single screening or screen records in duplicate; limited data extraction to only the most relevant information for our aims and objectives; and employed piloting and refinement of data extraction forms on a small portion of records.[20] Furthermore, we used the principles of SWiM to group and present information from both scans.[12]

A limitation of this work is that we only included registrations and funding records from 2020 onwards. Although this decision was made to capture upcoming or ongoing research, or trials

nearing completion, it has been noted that there was a decrease in trial registrations in Europe during the pandemic, with trial numbers remaining below the 2019 average until February 2021.[21] This correlates with the findings of this work, where clinical trial registrations in maternity services decreased between 2020 and 2021 before increasing again in 2022.

It should also be noted that, currently, clinical trial registrations and funding records tend to contain few details, with funding records normally only reporting a brief abstract or plain language summary. We attempted to gather more information on clinical trial registrations and funding records by examining any associated or attached protocols. However, these were often not available, meaning data presented in this report is often based on a minimal amount of information and it may be that details surrounding outcomes, subgroups and how domains of the PROGRESS-Plus are set to be addressed are not presented.

Within these horizon scans, we only included RCTs, CCTs and observational studies of interventions. This excludes qualitative and mixed-methods studies, as well as intervention design, process evaluations and implementation studies; we also did not extract information for these designs if they were included as part of a wider work programme. During screening, we excluded 982 records as they had an ineligible study design (30% of all records screened). As such, the information here is only reflective of upcoming trials that aim to evaluate an intervention and may not be fully reflective of the whole breadth of research surrounding maternity services within the UK.

Furthermore, although we only found a small amount of records reporting adverse events as an outcome of interest (26% in the clinical trials scan and 32% in the funding scan), it is possible that adverse events are not documented as a formal outcome measure as part of these records but are collected during the planned trial. Neither the current World Health Organization Trial Registration Data Set (Version 1.3.1) nor the guidance from the ISRCTN registry mandate the types of outcome measures to be included within trial registrations, only how they should be reported.[22,23]

Conclusions

We identified 31 clinical trial registrations and 34 funding records either entirely or partly set within maternity services in the UK posted since 2020. Most of the records we identified were centred on antenatal care. Very few clinical trial registrations or funding records stated that they aimed to assess PROMs or PREMs and we found little evidence of consideration of PROGRESS-Plus domains. Future research within maternity services should include PROMs and PREMs and state how different domains of the PROGRESS-Plus framework will be applied to the research.

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Appendix A: Search strategies for clinical trials scan

Table 1: Summary of results

Database	Search date	# results
ClinicalTrials.gov	13/03/2024	1669
ICTRP	13/03/2024	1673
Total *before* de-duplication		3342
Total *after* de-duplication		2823

Table 2: ClinicalTrials.gov

Recruiting, Not yet recruiting, Active, not recruiting, Completed Studies | Start date on or after 01/01/2020

#	String	Results
1	antenatal care OR antenatal OR obstetrics OR postnatal care OR postnatal OR maternity OR maternity care OR maternity services OR prenatal care OR prenatal OR birth	1669

Table 3: WHO ICTRP Search Portal

Recruitment status: ALL | Date of registration 01/01/2020 to 13/03/2024

#	String	Results
1	“antenatal care” OR antenatal OR obstetrics OR “postnatal care” OR postnatal OR maternity OR “maternity care” OR “maternity services” OR “prenatal care” OR prenatal OR birth	1673

Appendix B: Search strategies for funding source scan

Table 1: Summary of results

Database	Search date	# results	# Dedup
NIHR	18/03/2024	420	219
GtR (ukri.org)	18/03/2024	845	677
Europe PMC	19/03/2024	1606	1583
360 Giving	18/03/2024	1015	815
Total *before* de-duplication		3886	
Total *after* de-duplication			3294

Table 2: NIHR Funding and Awards

Individual keyword search | Start year: 2020, 2021, 2022, 2023, 2024

#	String	Results
1	"antenatal care" | antenatal | obstetrics | "postnatal care" | postnatal | maternity | "maternity care" | "maternity health" | "maternity services" | "prenatal care" | prenatal | birth	420

Table 3: UK Research and Innovation Gateway (UKRI GtR)

Individual keyword search | Start year: 2020, 2021, 2022, 2023, 2024

#	String	Results
1	"antenatal care" | antenatal | obstetrics | "postnatal care" | postnatal | maternity | "maternity care" | "maternity health" | "maternity services" | "prenatal care" | prenatal | birth	845

Table 4: 360 Giving

Individual keyword search | Award date: 2020, 2021, 2022, 2023, 2024

#	String	Results
1	"antenatal care" | antenatal | obstetrics | "postnatal care" | postnatal | maternity | "maternity care" | "maternity health" | "maternity services" | "prenatal care" | prenatal | birth	1015

Table 5: Europe PMC

#	String	Results
1	(TITLE:"postnatal care") AND (FIRST_PDATE:[2020 TO 2024])	282
2	(TITLE:"maternity care") AND (FIRST_PDATE:[2020 TO 2024])	686
3	(TITLE:"maternity health") AND (FIRST_PDATE:[2020 TO 2024])	14
4	(TITLE:"maternity services") AND (FIRST_PDATE:[2020 TO 2024])	124
5	(TITLE:"prenatal care") AND (FIRST_PDATE:[2020 TO 2024])	500
	Total	1606

Appendix C: Overview of included clinical trials and funding

Table 1: Included clinical trials

NCT number	Sponsor/ Funder	Study design	UK only?	Service type	Targeted population?	Outcomes	PROGRESS-Plus domains
NCT04595214	Other	Observational	N	Antenatal	Twin pregnancy	Adverse events Laboratory outcomes Birth outcomes	None
NCT04586283	Other	Observational	Y	Antenatal	No	Physical health Mental health	None
NCT04480684	Other	Observational	Y	Postnatal	Childbirth-related perineal injury and wound infection	Physical health Laboratory outcomes	None
NCT04336878	Other	RCT	Y	Antenatal	Overweight or obese	Feasibility outcomes	Personal characteristics
NCT04635410	Other	Observational	Y	Perinatal	No	Birth outcomes	None
NCT04745494	Other	RCT	Y	Postnatal	No	Mental health Laboratory outcomes	None
NCT04393259	Other	Observational	Y	Antenatal and Postnatal	No	Mental health Birth outcomes	None
NCT05154578	Industry	RCT	N	Antenatal	No	Physical health Adverse events Laboratory outcomes	None
NCT04941534	Industry	Observational	Y	Antenatal	No	Physical health	None
NCT05137808	Other	Observational	Y	Postnatal	Risk of cardiovascular disease	Physical health	Race/ethnicity/culture / language Personal characteristics
NCT05434195	Other	RCT	Y	Antenatal	No	Laboratory outcomes Feasibility outcomes	None
NCT05628675	Other	Single-arm	Y	Antenatal	Antenatal depression	Mental health	None
NCT05983029	Other	Observational	Y	Perinatal	No	Birth outcomes	None
NCT06053697	Other	Observational	Y	Perinatal	Twin pregnancy	Birth outcomes	None

NCT number	Sponsor/ Funder	Study design	UK only?	Service type	Targeted population?	Outcomes	PROGRESS-Plus domains
NCT05751031	Charity	Observational	N	Antenatal	HIV-positive	Adverse events Birth outcomes	Personal characteristics
NCT06143046	Industry	RCT	N	Antenatal	No	Adverse events Laboratory outcomes Birth outcomes	None
NCT06259305	Other	Observational	Y	Antenatal	Experiencing a pregnancy where the baby is unlikely to survive to full term or a comfort care only plan has been agreed	Feasibility outcomes	None
DRKS00023441	Government	Single-arm	N	Antenatal	Twin pregnancy	Physical health Adverse events Laboratory outcomes Birth outcomes	None
ISRCTN10833250	Government	RCT	Y	Antenatal	No	Physical health Feasibility outcomes	None
ISRCTN12258825	Charity	RCT	Y	Antenatal and Postnatal	Couples expecting first baby	Mental health	None
ISRCTN26790237	Government	RCT	Y	Perinatal	Band 5, 6 and 7 community midwives	Service metrics	None
ISRCTN26523605	Charity	RCT	Y	Perinatal	1. Midwifery and obstetric clinicians 2. Women giving birth	Birth outcomes Service metrics Feasibility outcomes	None
ISRCTN59959611	Government	RCT	Y	Perinatal	Twin pregnancy	Physical health Birth outcomes Feasibility outcomes	None
ISRCTN66445401	Charity	RCT	Y	Antenatal, Perinatal and Postnatal	No	Mental health Birth outcomes Feasibility outcomes	Place of residence Race/ethnicity/culture / language
ISRCTN12196131	Charity	Quasi-experimental	Y	Antenatal, Perinatal and Postnatal	No	Mental health Birth outcomes	None

NCT number	Sponsor/ Funder	Study design	UK only?	Service type	Targeted population?	Outcomes	PROGRESS-Plus domains
ISRCTN41632964	Charity	RCT	Y	Antenatal and Perinatal	No	Physical health Adverse events Birth outcomes	None
ISRCTN10781027	Government	RCT	Y	Postnatal	No	Mental health Adverse events Feasibility outcomes	None
ISRCTN17679951	Government	RCT	Y	Perinatal and Postnatal	No	Physical health Mental health Adverse events Laboratory outcomes Service metrics	None
ISRCTN90686599	Government	RCT+ Non-randomised	Y	Antenatal	Gestational diabetes	Physical health Adverse events Laboratory outcomes Feasibility outcomes	Gender/sex
ISRCTN12754931	Government	RCT	Y	Antenatal	High levels of RNT and anxiety up to a moderate level	Mental health	None
ISRCTN69012026	Government	RCT	Y	Antenatal	Above clinical threshold on a standard anxiety screening measure (GAD-7)	Mental health Service metrics	Gender/sex
Abbreviations: GAD=7 = General Anxiety Disorder-7; FNAIT = foetal and neonatal alloimmune thrombocytopenia; RCT = randomised controlled trial; RNT = repetitive negative thinking; UK = United Kingdom							

Table 2: Included funding records

Title	Funder	Study design	Service type	Targeted population?	Outcomes	PROGRESS-Plus domains
A randomised controlled trial of a web-based early intervention targeting repetitive negative thinking (RNT) in pregnant women: an evaluation of its impact on perinatal anxiety and the mechanism of change	NIHR	RCT	Antenatal	High RNT and low to moderate anxiety on the GAD-7	Mental health Feasibility outcomes	None
A Randomised Placebo-Controlled Trial of Antenatal Corticosteroids for Planned Birth in Twins: STOPPIT-3	NIHR	RCT	Antenatal	Twin pregnancy	Physical health Adverse events Feasibility outcomes	None
ACORN: A multi-site randomised COntrolled trial to evaluate the impact of a group tReatment for aNtenatal anxiety	NIHR	RCT	Antenatal	No	Mental health	Place of residence Socioeconomic status
Active music-making in the perinatal period: impact on mental health and wellbeing.	AHRC	Observational	Perinatal	No	Mental health	None
Atosiban versus placebo in the treatment of late threatened preterm birth. APOSTEL VIII study	NIHR	RCT	Perinatal	Threatened preterm birth	Adverse events Laboratory outcomes Birth outcomes	None

Title	Funder	Study design	Service type	Targeted population?	Outcomes	PROGRESS-Plus domains
BabyBreathe Trial (A randomised controlled trial of a complex intervention to prevent return to smoking postpartum)	NIHR	RCT	Antenatal	Pregnant women who have quit smoking in the 12 months before or during pregnancy	Physical health Mental health	None
Calcium Supplementation for Prevention of Pre-eclampsia in High Risk Women: CaPE Trial	NIHR	RCT	Antenatal	No	Physical health Adverse events Laboratory outcomes Birth outcomes Service metrics	None
Clinical Decision Tool to Reduce Placental Disorders in Pregnancy - a multi-centre cluster RCT	NIHR	Cluster-RCT	Antenatal	No	Birth outcomes	None
Digital Assessment of Wellbeing in New Parents (DAWN-P): a feasibility study of digital screening for postnatal depression	NIHR	Feasibility RCT	Antenatal and postnatal	New parents	Mental health Feasibility outcomes	None
Does a guided relaxation audio track increase yield of expressed milk and breastfeeding rates in mothers of very preterm infants? A small randomised controlled trial and nested exploratory work	NIHR	RCT	Postnatal	Mothers of very preterm infants	Mental health	None

Title	Funder	Study design	Service type	Targeted population?	Outcomes	PROGRESS-Plus domains
Effect of an intermittent low energy diet on glycaemic control and the requirement for anti-diabetic medication in women with gestational diabetes: a feasibility study.	NIHR	Feasibility RCT	Antenatal	Women with obesity and gestational diabetes	Physical health Laboratory outcomes Feasibility outcomes	None
FERN: Intervention or Expectant Management for Early Onset Selective Fetal Growth Restriction in Monochorionic Twin Pregnancy	NIHR	Feasibility RCT	Antenatal	Twin pregnancy	Feasibility outcomes	None
First-trimester Placental Ultrasound Study (First PLUS): an observational cohort study to assess the clinical utility of the OxNNet Toolkit for the prediction of adverse pregnancy outcomes.	NIHR	Observational	Antenatal	No	Adverse events Laboratory outcomes Birth outcomes	None
Magnetic resonance Imaging of mother and fetus in late gestation to inform and optimise BIRTH management: the MIBIRTH study	MRC	Observational	Antenatal	Women with a higher risk of adverse delivery	Physical health Mental health Birth outcomes	None
Novel Biomarker Test with Treatment, to Predict and Prevent Miscarriage and Adverse Birth Outcomes in Ethnically Diverse Patient Populations.	Innovate UK	RCT	Perinatal	No	Adverse events	Race/ ethnicity/ culture/ language

Title	Funder	Study design	Service type	Targeted population?	Outcomes	PROGRESS-Plus domains
Open-label randomised controlled trial of nicotine replacement therapy (NRT) for preloading, lapse recovery and smoking reduction: impact on smoking in pregnancy	NIHR	RCT	Antenatal	Women who smoke more than 5 daily cigarettes (> 10 before pregnancy)	Physical health Birth outcomes Service metrics	None
Optimising the management of blood pressure following hypertensive pregnancy to reduce cardiovascular risk	NIHR	RCT	Postnatal	Women requiring postnatal antihypertensive treatment	Physical health	Race/ ethnicity/ culture/ language Socioeconomic status
Options: An intervention development and feasibility study to predict, and provide choices for avoiding, emergency caesarean in nulliparous women.	NIHR	Observational with nested feasibility RCT	Antenatal	Observational: No Nested RCT: Women at a high risk of emergency caesarean section	Mental health Feasibility outcomes	None
Perinatal emotional skills groups for women with borderline personality disorder: a randomised feasibility trial	NIHR	Feasibility RCT	Antenatal and postnatal	Women with a likely diagnosis of BPD and are either pregnant or are within 12 months of having a live birth.	Mental health Adverse events Birth outcomes Feasibility outcomes	None
Physiological breech birth: a feasibility study for a pragmatic trial	NIHR	Feasibility RCT	Antenatal and perinatal	Pregnant women with a breech-presenting foetus	Feasibility outcomes	None

Title	Funder	Study design	Service type	Targeted population?	Outcomes	PROGRESS-Plus domains
PRAMS: Peer-support to Reduce Antenatal Maternal Smoking. Development and feasibility testing of a social media group to provide peer support and enhance quit rates for women who smoke in pregnancy.	NIHR	Feasibility RCT	Antenatal	Pregnant women who smoke	Feasibility outcomes	None
PravastatIn tO preveNt prEtErm biRth (PIONEER): a parallel group randomised placebo-controlled trial	NIHR	RCT	Antenatal	Pregnant women at high risk for preeclampsia	Adverse events Birth outcomes	None
Pregnancy AntihyperteNsive Drugs: which Agent is best? (giant PANDA study)	NIHR	RCT	Antenatal	Pregnant women with hypertension	Physical health Adverse events Birth outcomes Service metrics	None
PROTECT PRegnancy Outcomes using continuous glucose monitoring TEChnology in pregnant women with Type 2 diabetes: A multicentre randomised controlled trial of the clinical and cost-effectiveness of using continuous glucose monitoring in pregnant women with type 2 diabetes	NIHR	RCT	Antenatal	Pregnant women with type 2 diabetes, HbA1c of ≥43 mmol/mol (6.1%) in pregnancy (≤14 weeks' gestation)	Physical health Adverse events Laboratory outcomes Service metrics	Race/ ethnicity/ culture/ language

Title	Funder	Study design	Service type	Targeted population?	Outcomes	PROGRESS-Plus domains
RECOGNISE taRgeted intermittEnt gluCose mOnitoring for the management of GestatioNal dIabeteS mEllitus A Feasibility Study	NIHR	Feasibility RCT	Antenatal	Pregnant women, singleton pregnancy, recent diagnosis of GDM (within 14 days of commencing medication, up to 34 weeks gestation) prescribed metformin and/or insulin.	Adverse events Feasibility outcomes	None
ROTATE Rotation of the fetal head at full cervical dilatation	NIHR	RCT	Perinatal	No	Mental health Adverse events Birth outcomes Feasibility outcomes	None
Smoking cessation for pregnant women with moderate to severe mental illness: Intervention adaptation and feasibility trial	NIHR	Feasibility RCT	Antenatal	Pregnant women who smoke and have moderate to severe mental illness	Physical health Feasibility outcomes	None
STARshiP: Screen and Treat with Aspirin to Reduce Pre-eclampsia	NIHR	RCT	Antenatal	No	Birth outcomes	Gender/ sex
The effectiveness and cost-effectiveness of Assets-based feeding help Before and After birth (ABA-feed) for improving breastfeeding initiation and continuation	NIHR	RCT	Antenatal and postnatal	No	Mental health	None

Title	Funder	Study design	Service type	Targeted population?	Outcomes	PROGRESS-Plus domains
The 'PANDA' research programme: Primary prevention of maternal ANaemia to avoid preterm Delivery and other Adverse outcomes	NIHR	RCT	Antenatal and postnatal	No	Birth outcomes	None
The RAPID 2 study. Reducing Anxiety in Pregnancy: Intervention Development phase 2. A feasibility study of a midwife facilitated supportive intervention.	NIHR	Feasibility RCT	Antenatal	Pregnant women with self-reported symptoms of mild to moderate anxiety	Mental health Birth outcomes	Race/ ethnicity/ culture/ language
The use of Advanced MRI techniques to evaluate antenatal lung development.	MRC	Observational	Antenatal	100 women: no 70 women: high risk of pulmonary hyperplasia	Physical health Service metrics	None
Untreated depression or antidepressant use during pregnancy: what are the outcomes?	Wellcome Trust	Observational	Antenatal	No	Birth outcomes	None
Validation of Early Warning Systems for Severe Maternal Morbidity and Individualised Prediction of Severe Maternal Morbidity within Ethnic Groups	MRC	Observational	Antenatal	Women from all ethnic groups who are unwell during or after pregnancy	Physical health	Race/ ethnicity/ culture/ language
Abbreviations: AHRC = Arts and Humanities Research Council; BPD = Borderline Personality Disorder; GAD=7 = General Anxiety Disorder-7; GDM = gestational diabetes mellitus; MRC = Medical Research Council; NIHR = National Institute for Health and Care Research; RCT = randomised controlled trial; RNT = repetitive negative thinking; UK = United Kingdom						

Appendix D: Interventions and comparators

Table 1: Interventions and comparators in included clinical trial registrations

Trial record	Intervention	Comparator (if applicable)
NCT04595214	MC twin anaestemosis separatio by laser Vasa previa and placenta accreta treated with steroids or other protocols Positive trisomies by NIPS undergo CVS or amniocentesis	N/A - observational
NCT04586283	Maternal prone position	N/A – observational
NCT04480684	Three-dimensional endoanal ultrasound Transperineal ultrasound (multiplanar) MolecuLight i:X (bacetrial autofluorescence camera) Silhoutte® 3D Camera (three-dimensional wound measuring camera)	N/A - observational
NCT04336878	Healthy Habits in Pregnancy and Beyond: habit-based intervention to support development of 10 healthy dietary and activity behaviours of pregnant women with overweight or obesity	No intervention: usual antenatal care
NCT04635410	Ultrasound imaging: scan labouring women by ultrasound	N/A - observational
NCT04745494	Oxytocin nasal administration: single dose 40.32 ug Syntocinon	Placebo: single dose, nasal administration
NCT04393259	Rainbow Clinic Model of Care: antenatal model of care with initial ultrasound scan at 23 weeks' gestation including uterine artery Doppler. Frequency of subsequent scans determined using data from initial scan. Continuity of care provided by obstetricians and midwives.	N/A - observational

Trial record	Intervention	Comparator (if applicable)
NCT05154578	1. 1 placebo injection at 22 (±1) weeks' gestation, 1 injection GBS-NN/NN2 at 26 (±1) weeks gestation, and 1 injection of GBS- NN/NN2 at 30 (±1) weeks gestation 2. 1 injection GBS-NN/NN2 at 22 (±1) weeks gestation, 1 injection of GBS-NN/NN2 at 26 (±1) weeks gestation and 1 injection of placebo at 30 (±1) weeks gestation 3. 1 injection of GBS-NN/NN2 at 22 (±1) weeks gestation, 1 injection of placebo at 26 (±1) weeks gestation and 1 injection of GBS- NN/NN2 at 30 (±1) weeks gestation 4. 1 injection of placebo at 22 (±1) weeks gestation, 1 injection of GBS-NN/NN2 at 26 (±1) weeks gestation and 1 injection of placebo at 30 (±1) weeks gestation	Placebo injection
NCT04941534	Biorithim Research Kit system: foetal monitor, digital gateway and cloud storage to monitor maternal and foetal physiological parameters	N/A - observational
NCT05137808	Three days of consecutive home blood pressure monitoring every fornight from 2 to 12 weeks' postpartum	N/A - observational
NCT05434195	1. Low dose of 5-methyltetrahydrofolate (5-MTHF) 2. High dose of 5-methyltetrahydrofolate (5-MTHF)	1. No intervention (normotensive women) 2. Placebo (pre-eclampsia)
NCT05628675	Single-session 90-minute psychoeducational group ("Baby CHAT") delivered antenatally	N/A – single-arm trial
NCT05983029	1. Diagnostic test: intergluteal cleft 2. Diagnostic test: Neuraxial midline 3. Diagnostic test: horizontal distance between vertical markings	N/A - observational
NCT06053697	Vaginal swabs to assess the vaginal microbiome	N/A - observational
NCT05751031	Raltegravir exposure in pregnant women living with HIV in routine clinical care	N/A - observational

Trial record	Intervention	Comparator (if applicable)
NCT06143046	1. mRNA-1345 vaccination: dose A 2. mRNA-1345 vaccination: Dose B 3. mRNA-1345 vaccination: Dose C	Matched placebo
NCT06259305	Creation of a memory track combined with the baby's heartbeat	N/A - observational
DRKS00023441	Multi-marker, personalised, prenatal diagnostic model to predict feto-maternal complications in twins	N/A – single-arm trial
ISRCTN10833250	Antenatal midwife training package aimed at enhancing midwives' ability and motivation to inform and support women in practising pelvic floor muscle exercises	Standard antenatal care
ISRCTN12258825	Three sessions of couples' therapy in the antenatal period and two in the postnatal period	Usual care with no specific psychosocial intervention
ISRCTN26790237	1. E-learning package and post-questionnaire 2. Pre-questionnaire before doing e-learning package then questionnaire six months later 3. Place of Birth lead midwife in the team, as well as doing the e-learning package and post-questionnaire six months later 4. Place of Birth midwife in the team as well as pre-questionnaire, e-learning and post-questionnaire six months later	N/A – RCT with four arms
ISRCTN26523605	1. Sustainability arm: maternity units who have already adopted the OASI Care Bundle as part of OASI1 2. Peer support arm: OASI QI Leads of maternity units benefit from "peer support" facilitation model and receive continuous external support	Lean implementation arm: OASI QI Leads of maternity units will test the "lean" facilitation model and only receive the implementation toolkit and no external implementation support
ISRCTN59959611	Dexamethasone: two doses of 6.6 mg/2 ml solution administered 24 hours apart +/- 4 hours prior to the planned caesarean section or induction of labour	Matched placebo
ISRCTN66445401	Midwife-led continuity of care model: provides care in the antenatal, intrapartum and postnatal periods	Standard care

Trial record	Intervention	Comparator (if applicable)
ISRCTN12196131	Baby Steps: a "relationship-based" antenatal parent education programme mainly delivered in a group setting	Matched comparison group: did not take part in Baby Steps
ISRCTN41632964	Screening for pre-eclampsia at 35-36 weeks' gestation and planned early-term delivery if the risk for pre-eclampsia is increased	Usual care
ISRCTN10781027	CareLoop PND app: a digital screening tool to track mental health from study entry until 8 weeks' postpartum in addition to usual care	Usual care
ISRCTN17679951	OBS UK intervention: OBS UK postpartum haemorrhage care bundle, standardised documentation, introduced using quality improvement methods over 9-month period	Usual care
ISRCTN90686599	1. (Non-randomised): 1 metformin DR 900 mg tablet orally 3 to 8 hours prior to planned caesarean section 2. (Non-randomised): 1 metformin DR 900 mg tablet orally with or after breakfast and 1.5 hours (-1+2 hours) prior to commencement of blood sampling at clinical research facility 3. (Randomised, cross-over arm only): Continue own normal standard prescribed daily dose of metformin IR for first 7 days, then IMP metformin DR 900 mg tablet daily for 7 days at follow-up visit	3. (Randomised, cross-over arm only): 1 metformin DR 900 mg tablet daily for 7 days, then normal standard dose of metformin IR for 7 days
ISRCTN12754931	RELAX: 12 web-based CBM-I training sessions of 15-20 mins duration over 4 weeks, plus usual care	Usual care
ISRCTN69012026	CALM: four 2-hour online group sessions delivered to both the pregnant women/birthing person and their partner and one 2-hour postnatal reunion, plus usual care	Usual care

Table 2: Interventions and comparators in included funding records

Title	Intervention	Comparator (if applicable)
A randomised controlled trial of a web-based early intervention targeting repetitive negative thinking (RNT) in pregnant women: an evaluation of its impact on perinatal anxiety and the mechanism of change	Pregnancy-LENS + usual care: web-based intervention. Trains people with high repetitive negative thinking (RNT) to interpret uncertain/ ambiguous information in realistic and more positive ways.	Usual care
A Randomised Placebo-Controlled Trial of Antenatal Corticosteroids for Planned Birth in Twins: STOPPIT-3	Dexamethasone phosphate: 24 mg given by two injections 24 hours apart	Placebo: 24-72 hours before scheduled birth
ACORN: A multi-site randomised COntrolled trial to evaluate the impact of a group tReatment for aNtenatal anxiety	CALM + usual care: A 5-session group intervention that gives pregnant women tools to manage antenatal anxiety based on extensive consultation about their needs	Usual care
Active music-making in the perinatal period: impact on mental health and wellbeing.	Active music participation	NR
Atosiban versus placebo in the treatment of late threatened preterm birth. APOSTEL VIII study	Atosiban: intravenously, 6.75 mg/0.9 ml in one minute followed by a continuous infusion of 6 mg/hour for 45 hours	Placebo: intravenous normal saline at the same rate
BabyBreathe Trial (A randomised controlled trial of a complex intervention to prevent return to smoking postpartum)	BabyBreathe: a complex intervention with a combination of face to face, digital and tailored support	Usual care
Calcium Supplementation for Prevention of Pre-eclampsia in High Risk Women: CaPE Trial	Calcium 2 g/day from 12 to 22 weeks' gestation until delivery, plus usual care	Placebo tablets plus usual care
Clinical Decision Tool to Reduce Placental Disorders in Pregnancy - a multi-centre cluster RCT	Tommy's App: medical device using clinically-validated AI-based algorithms to provide more accurate and personalised pregnancy risk assessment	Standard care
Digital Assessment of Wellbeing in New Parents (DAWN-P): a feasibility study of digital screening for postnatal depression	ClinTouch DAWN-P: a smartphone app that allows parents to monitor their mood on a daily basis from 36 weeks gestation	Usual care

Title	Intervention	Comparator (if applicable)
Does a guided relaxation audio track increase yield of expressed milk and breastfeeding rates in mothers of very preterm infants? A small randomised controlled trial and nested exploratory work	15-minute soundtrack while expressing milk for 21 days or as long as desired	Usual care
Effect of an intermittent low energy diet on glycaemic control and the requirement for anti-diabetic medication in women with gestational diabetes: a feasibility study.	Low-energy diet (ILED) and physical activity advice, plus standard care	Physical activity advice plus standard care
FERN: Intervention or Expectant Management for Early Onset Selective Fetal Growth Restriction in Monochorionic Twin Pregnancy	Intervention: to be determined by another work package	Non-intervention: to be determined by another work package
First-trimester Placental Ultrasound Study (First PLUS): an observational cohort study to assess the clinical utility of the OxNNet Toolkit for the prediction of adverse pregnancy outcomes.	OxNNet: Toolkit to examine placental metrics for prediction of foetal growth restriction	N/A - observational
Magnetic resonance Imaging of mother and fetus in late gestation to inform and optimise BIRTH management: the MIBIRTH study	Magnetic resonance imaging (MRI) after 36 weeks gestation plus an ultrasound scan	N/A - observational
Novel Biomarker Test with Treatment, to Predict and Prevent Miscarriage and Adverse Birth Outcomes in Ethnically Diverse Patient Populations.	Test for adverse pregnancy outcomes	NR

Title	Intervention	Comparator (if applicable)
Open-label randomised controlled trial of nicotine replacement therapy (NRT) for preloading, lapse recovery and smoking reduction: impact on smoking in pregnancy	i) NRT patch offered as 'preloading', used up to 4 weeks before Quit Date, after which usual care support begins ii) After usual care support begins and women receive NRT to help them quit as part of this, participants are advised to continue NRT should they experience any brief smoking lapses. For intervention arm women who are still smoking 6 weeks from randomisation: iii) NRT offered as patch or inhalator and used to reduce smoking and induce cessation	Usual care
Optimising the management of blood pressure following hypertensive pregnancy to reduce cardiovascular risk	Blood pressure self-management	NR
Options: An intervention development and feasibility study to predict, and provide choices for avoiding, emergency caesarean in nulliparous women.	Options: a digital tool to predict risk of emergency caesarean section at 36 weeks in nulliparous women	Usual care
Perinatal emotional skills groups for women with borderline personality disorder: a randomised feasibility trial	Perinatal emotional skills group (ESG): Emotional skills groups can help people to learn new skills in managing their feelings and relationships and these groups can relieve some of the symptoms of Borderline Personality Disorder.	Usual care
Physiological breech birth: a feasibility study for a pragmatic trial	OptiBreech collaborative care: OptiBreech Care is a care pathway for breech presentation at term, including where chosen, physiological breech birth attended by professionals with advanced training and/or proficiency.	Usual care

Title	Intervention	Comparator (if applicable)
PRAMS: Peer-support to Reduce Antenatal Maternal Smoking. Development and feasibility testing of a social media group to provide peer support and enhance quit rates for women who smoke in pregnancy.	Online interactive group to successfully support public health behaviour change activities	Usual care
PravastatIn tO preveNt prEtErm biRth (PIONEER): a parallel group randomised placebo-controlled trial	10 mg of pravastatin	Placebo
Pregnancy AntihyperteNsive Drugs: which Agent is best? (giant PANDA study)	Oral nifedipine modified release preparations (no brand specified) to be taken twice daily.	Active control: Oral labetalol (no brand specified) to be taken twice to three times daily
PROTECT PRegnancy Outcomes using continuous glucose monitoring TEChnology in pregnant women with Type 2 diabetes: A multicentre randomised controlled trial of the clinical and cost-effectiveness of using continuous glucose monitoring in pregnant women with type 2 diabetes	A Real-Time Continuous Glucose Monitoring (CGM) system	Standard clinical care, which may be finger-prick Self-Monitoring Blood Glucose (SMBG) or continuous glucose monitoring.
RECOGNISE taRgeted intermittEnt gluCose mOnitoring for the management of GestatioNal dIabeteS mEllitus A Feasibility Study	isCGM device (Freestyle Libre2) and smartphone/reader: The isCGM device-FreeStyle Libre2 sensor is a second-generation Libre device. It consists of an integrated transmitter and sensor, packaged with a disposable self-insertion kit. The sensor reads to a mobile phone app (or a reader for people without a compatible phone). The device measures interstitial glucose through the small sensor inserted on the back of the upper arm to provide real-time glucose readings.	Standard care using self-monitored blood glucose

Title	Intervention	Comparator (if applicable)
ROTATE Rotation of the fetal head at full cervical dilatation	Manual Rotation: Rotation of the fetal head by manual rotation - followed by direct forceps or direct ventouse or maternal effort. The instrument to be used for direct traction after the rotation is at the choice of the obstetrician and will be recorded for further analysis on the Day 0 CRF.	Instrumental rotation: Rotation of the fetal head by rotational instrument (rotational forceps or rotational ventouse) at the choice of the obstetrician. Instrument to be used for direct traction after the rotation at the choice of the obstetrician – usually the same type of instrument (forceps or ventouse), but use of maternal effort after rotation by instrument is also possible.
Smoking cessation for pregnant women with moderate to severe mental illness: Intervention adaptation and feasibility trial	Unspecified smoking cessation intervention	Standard care
STARshiP: Screen and Treat with Aspirin to Reduce Pre-eclampsia	The FMF screening test, an algorithm involving uterine artery Doppler ultrasound measures, PlGF blood test, maternal blood pressure and risk factors.	Usual care by identification of maternal risk factors alone
The effectiveness and cost-effectiveness of Assets-based feeding help Before and After birth (ABA-feed) for improving breastfeeding initiation and continuation	Infant feeding helper service applying a proactive, assets-based, woman-centred approach, delivered antenatally and postnatally, tailored through face-to-face contacts, texts and telephone. A face-to-face contact at approximately 30 weeks of pregnancy will be followed by texts/brief calls.	Usual care
The 'PANDA' research programme: Primary prevention of maternal ANaemia to avoid preterm Delivery and other Adverse outcomes	Iron tablet	Placebo
The RAPID 2 study. Reducing Anxiety in Pregnancy: Intervention Development phase 2. A feasibility study of a midwife facilitated supportive intervention.	(a) One-to-one pre-group midwife meeting (b) Six facilitated group discussion sessions (c) Self-help materials.	Usual care

Title	Intervention	Comparator (if applicable)
The use of Advanced MRI techniques to evaluate antenatal lung development.	Advanced MRI techniques (deformable slice to volume reconstruction, motion corrected diffusion and T2* imaging) facilitate more accurate assessment of lung size and vasculature, and can assess tissue microstructure and oxygenation potentially reflecting alveolar structure and tissue perfusion.	N/A - observational
Untreated depression or antidepressant use during pregnancy: what are the outcomes?	Antidepressants	N/A - observational
Validation of Early Warning Systems for Severe Maternal Morbidity and Individualised Prediction of Severe Maternal Morbidity within Ethnic Groups	Early warning score: a system used in everyday medical care to identify women at risk of severe illness	N/A - observational

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