National Institute for Health and Care Excellence

Final

Postnatal care

[H] Tools for the clinical review of women

NICE guideline NG194

Evidence review underpinning recommendations 1.2.1 to 1.2.3, 1.2.8 to 1.2.12 and 1.2.17

April 2021

Final

These evidence reviews were developed by the National Guideline Alliance, part of the Royal College of Obstetricians and Gynaecologists

Disclaimer

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Local commissioners and/or providers have a responsibility to enable the guideline to be applied when individual health professionals and their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with those duties.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government, and Northern Ireland Executive. All NICE guidance is subject to regular review and may be updated or withdrawn.

ISBN: 978-1-4731-4078-3

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Tools for the clinical review of women

Review question

What tools for clinical review of women (including pain scores) are effective during the first 8 weeks after birth?

Introduction

With postnatal care extending across acute and community services, there is a need for consistency in how assessment of the wellbeing of the women is undertaken. Repeated surveys of women's experience with NHS postnatal services has identified a mismatch between how assessment is undertaken and their expectations. Pain and constipation in the postpartum period are common and can have an impact on daily living and wellbeing and can have severe short- and long-term consequences. The aim of this review is to identify clinical tools that are effective in assessing the woman's health, pain and constipation in particular, in the first 8 weeks after giving birth.

Summary of the protocol

Please see Table 1 for a summary of the Population, Intervention, Comparison and Outcome (PICO) characteristics of this review.

Table 1: Summary of the protocol (PICO table)

Population	Women who have given birth up to 8 weeks after birth.
Intervention	• Tool/checklist for the assessment of constipation applied in the postnatal period up to 8 weeks after birth (for example, the Bristol stool chart) • Maternal Pain Questionnaire or validated pain scores applied in the postnatal period up to 8 weeks after birth: - visual analogue scale - numeric rating scale - verbal categorical rating scale.
Comparison	• No tool/checklist/standard care • Different tool/checklist
Outcomes	**Critical** For all tools/checklists/scores: • maternal morbidity • maternal death (including suicide) • maternal re-attendance or admission to hospital. In addition, for pain scores: • depression • sexual distress scale. In addition, for constipation assessment tools: • constipation severity. **Important** • chronic pain.

For further details, see the review protocol in appendix A.

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual 2014. Methods specific to this review question are described in the review protocol in appendix A.

Declarations of interest were recorded according to NICE's 2014 conflicts of interest policy until March 2018. From April 2018 until June 2019, declarations of interest were recorded according to NICE's 2018 conflicts of interest policy. From July 2019 onwards, the declarations of interest were recorded according to NICE's 2019 conflicts of interest policy. Those interests declared before July 2019 were reclassified according to NICE's 2019 conflicts of interest policy (see Register of Interests).

Clinical evidence

Included studies

A systematic review of the literature was conducted but no studies were identified which were applicable to this review question.

See the literature search strategy in appendix B and study selection flow chart in appendix C.

Excluded studies

Studies not included in this review are listed, and reasons for their exclusion are provided in appendix K.

Summary of studies included in the evidence review

No studies were identified which were applicable to this review question (and so there are no evidence tables in appendix D). No meta-analysis was undertaken for this review (and so there are no forest plots in appendix E).

Quality assessment of clinical outcomes included in the evidence review

No studies were identified which were applicable to this review question and so there are no evidence profiles in appendix F.

Economic evidence

Included studies

A single economic search was undertaken for all topics included in the scope of this guideline but no economic studies were identified which were applicable to this review question. See the literature search strategy in appendix B and economic study selection flow chart in appendix G.

Excluded studies

No economic studies were reviewed at full text and excluded from this review.

Economic model

No economic modelling was undertaken for this review because, although the review question was considered priority for modelling, no clinical evidence that would allow development of an economic model was identified.

Evidence statements

Clinical evidence statements

No evidence was identified which was applicable to this review question.

Economic evidence statements

No economic evidence was identified which was applicable to this review question.

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

The committee rated maternal death, maternal morbidity and maternal re-attendance or admission to hospital as critical outcomes. The committee agreed it would have been important for their decision making to know whether the use of one tool or another results in the identification of signs or symptoms that may lead to any of these critical outcomes. These critical outcomes were chosen as they are often preventable and early warning systems may improve maternal outcomes.

In addition, the committee rated the following outcomes as critical, in respect of specific tools: depression and sexual distress – for a pain assessment tool and constipation severity – for a constipation assessment tool. The committee also rated chronic pain as an important outcome.

The potential long-term impact of sub-optimal postnatal pain management on maternal health, breast feeding rates, mother and baby bonding, sexual distress and chronic pain require these to be identified and addressed.

No relevant evidence was located, therefore the committee had no data on any of these outcomes to use as a basis for discussions or making recommendations.

The quality of the evidence

No studies were identified which were applicable to this review question.

Benefits and harms

Because of the lack of evidence, the committee were not able to recommend any specific tools for the assessment of pain or constipation in women in the first 8 weeks after birth but a research recommendation was made so that future research could identify clinical tools that could be useful in the assessment of the health of women in the postpartum period. See appendix L for more details.

Based on discussion around evidence review J on perineal pain, the committee recommended that a validated pain scale could be used to monitor perineal pain over time. Based on evidence review F on the content of postnatal contacts, the committee drafted recommendations which relate to the assessment of women's health. The committee agreed that routine postnatal contact by all healthcare professionals should include an assessment of the general health and wellbeing of the woman, including discussion about symptoms and signs of potential postnatal physical and mental health problems. The woman's psychological and emotional health should also be assessed at every contact. At every postnatal contact with a midwife, there should be an assessment of symptoms and signs of infection, pain, vaginal discharge and bleeding, bladder function, bowel function (including constipation), breast comfort, symptoms and signs of thromboembolism, anaemia and pre-eclampsia,

perineal healing for those who had a vaginal birth and wound healing for those who had caesarean section.

The committee discussed that women often suffer needlessly with postnatal pain and discomfort. The committee highlighted that health care professionals are at risk of working on the basis that a significant amount of discomfort post birth is 'to be expected' and does not need treating. In fact, these are health issues that should be treated and therefore should be appropriately assessed. The benefit of assessing the woman's health would be to identify concerns in the early stages and intervening earlier, as opposed to not identifying the problems until later on where the issues have worsened, causing distress and requiring intensive resources. However, there is a small risk of overtreatment if women receive treatment when their symptoms may have naturally resided with time resulting in potentially unnecessary intervention.

The committee agreed that assessing pain was of particular importance, because if women are judged to 'look comfortable' they are assessed as not being in pain. Postnatal pain is 'normalised' and therefore most often not treated. The committee therefore wanted to ensure that any assessment of a woman's health in the postnatal period includes talking to the woman about how she is feeling and about how her symptoms are affecting her daily life. The committee were aware that every woman's experience of pain and distress is different, and their level of discomfort would be subjective too.

The committee acknowledged that certain specific health conditions are covered by other NICE guidelines. Therefore, for women with sepsis, hypertension, diabetes, thromboembolism, and urinary incontinence and pelvic organ prolapse, the committee agreed to cross refer to the NICE guidelines for details specific to assessment in these conditions.

Cost effectiveness and resource use

No economic evidence is available for this review question. The committee agreed that spending time at postnatal contacts to ask women about their physical and mental health and emotional wellbeing, including, for example, assessment of pain, symptoms and signs of infection, bladder and bowel function, and other clinical conditions that may develop after giving birth, has low-to-moderate resource implications (health professional time). However, assessment and monitoring of women's health may lead to improved health and quality of life for the woman and cost-savings to the health service, because this approach allows symptoms to be managed appropriately at an early stage, before they become more severe and require a more costly intervention. Therefore, the committee agreed that the recommendations ensure efficient use of healthcare resources.

References

No evidence was identified which was applicable to this review question.

Appendices

Appendix A – Review protocol

Review protocol for review question: What tools for clinical review of women (including pain scores) are effective during the first 8 weeks after birth?

Table 2: Review protocol

Field (based on PRISMA-P)	Content
Review question	What tools for clinical review of women (including pain scores) are effective during the first 8 weeks after birth?
Type of review question	Intervention
Objective of the review	This review aims to determine what tools for clinical review of women are effective during the first 8 weeks after birth.
Eligibility criteria – population/disease/condition/issue/domain	Women who have given birth up to 8 weeks after birth. The following populations will be excluded: - women admitted to intensive care after labour and birth and women returning to theatre following a caesarean section - women experiencing these complications intrapartum: massive obstetric haemorrhage; fourth degree tear; caesarean hysterectomy; uterine artery embolisation due to haemorrhage; bladder, ureteric, blood vessel, or bowel injury at Caesarean section; sepsis; venous thromboembolism - women with these complications in pregnancy: gestational diabetes; pre-eclampsia; pregnancy induced hypertension; acute fatty liver of pregnancy - women with pre-existing conditions (for example, type 1 diabetes, type 2 diabetes, essential hypertension; solid organ transplant recipients; renal disease (usually related to hypertension or

Field (based on PRISMA-P)	Content
	autoimmune causes); any form of malignancy; sickle cell disease; thalassaemia; cardiac disease; poorly controlled epilepsy; stroke; cerebral venous thrombosis; sub-arachnoid haemorrhage.
Eligibility criteria – intervention(s)/exposure(s)/prognostic factor(s)	• Tool/checklist for the assessment of constipation applied in the postnatal period up to 8 weeks after birth (for example, the Bristol stool chart) • Maternal Pain Questionnaire or validated pain scores applied in the postnatal period up to 8 weeks after birth: - visual analogue scale - numeric rating scale - verbal categorical rating scale. Tools used for the assessment of incontinence and prolapse will be excluded because the NICE guideline on urinary incontinence in women (CG171) and the related update (yet to be published) cover assessment and investigation of urinary incontinence and prolapse. Tools used for recognising mental health problems will be excluded from this review because the NICE guideline on antenatal and postnatal mental health (CG192) already covers recognition of mental health problems in the postnatal period. Tools used for the identification of sepsis will be excluded from this review because the NICE guideline on sepsis (NG51) already covers this. Tools used for the identification of early signs and symptoms of secondary postpartum haemorrhage will be excluded from this review because a separate review in this guideline already covers this.
Eligibility criteria – comparator(s)/control or reference (gold) standard	• No tool/checklist/standard care • Different tool/checklist
Outcomes and prioritisation	For all tools/checklists/scores: **Critical** • maternal morbidity (default MIDs) • maternal death (including suicide) (any statistically significant difference)

Field (based on PRISMA-P)	Content
	• maternal re-attendance or admission to hospital (default MIDs). In addition, for constipation assessment tools: **Critical** • constipation severity (default MIDs). In addition, for pain scores: **Critical** • depression (default MIDS) • sexual distress scale (default MIDS). **Important** • chronic pain (default MIDs). Outcomes should be measured after a time interval which is long enough for any relevant clinical interventions to have been implemented after the use of the assessment tool – this should be specified in the study; alternatively this will be discussed with the committee (please note that time frames are important to interpret outcome data, because better detection could lead to an initial increase in adverse outcomes, but to a long-term decrease thank to earlier intervention).
Eligibility criteria – study design	Include published full text papers: • systematic reviews • RCTs • only if RCTs are unavailable: prospective or retrospective comparative cohort studies (with a sample size >100) • prospective study designs will be prioritised over retrospective study designs. Exclude: • conference abstracts • cohort studies with a sample size <100 • case-control studies and case series.

Field (based on PRISMA-P)	Content
Other inclusion exclusion criteria	Studies from low- and middle-income countries will be excluded Date: published from 2000. Practice has changed since 2000 and anything published before this is unlikely to be relevant.
Proposed sensitivity/sub-group analysis, or meta-regression	Groups that will be reviewed and analysed separately: • first-time mothers versus others • young women (19 years or under) • women with physical or cognitive disabilities • women with mental illness • women who have difficulty accessing postnatal care services • women with alcohol or substance misuse. In the presence of heterogeneity, the following subgroups will be considered for sensitivity analysis: • instrumental vs non-instrumental vaginal birth vs caesarean section. Statistical heterogeneity will be assessed by visually examining the forest plots and by calculating the I^2 inconsistency statistic (with an I^2 value of more than 50% indicating considerable heterogeneity) Potential confounders: • age • BMI • parity • language.
Selection process – duplicate screening/selection/analysis	This review question was prioritised for health economic analysis therefore formal dual weeding (title and abstract) of 10% of items will be undertaken. Any discrepancies will be resolved through discussion between the first and second reviewers or by reference to a third person. (Moreover, internal (NGA) quality assurance processes will include consideration of the outcomes of weeding, study selection and data extraction and the committee will review the results of study selection and data extraction).
Data management (software)	Pairwise meta-analyses will be performed using Cochrane Review Manager (RevMan5).

Field (based on PRISMA-P)	Content
	'GRADEpro' will be used to assess the quality of evidence for each outcome.
Information sources – databases and dates	The following databases will be searched: • CCRCT • CDSR • DARE • Embase • Emcare • HTA • Medline • Medline in process • NHS EED. Searches will be restricted by: • Date limitations: 2000 to 4th December 2019 • English language
Identify if an update	This guideline will update the NICE guideline on postnatal care up to 8 weeks after birth (CG37). All reviews are being conducted afresh. The CG37 (2006) guideline included multiple recommendations on reviewing women's health.
Author contacts	https://www.nice.org.uk/guidance/indevelopment/gid-ng10070
Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual
Search strategy – for one database	For details please see appendix B.
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables).
Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables).

Field (based on PRISMA-P)	Content
Methods for assessing bias at outcome/study level	Standard study checklists were used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/
Criteria for quantitative synthesis	For details please see section 6.4 of Developing NICE guidelines: the manual
Methods for quantitative analysis – combining studies and exploring (in)consistency	For a full description of methods see Supplement 1.
Meta-bias assessment – publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual.
Confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual
Rationale/context – what is known	For details please see the introduction to the evidence review.
Describe contributions of authors and guarantor	A multidisciplinary committee developed the guideline. The committee was convened by The National Guideline Alliance and chaired by Dr David Jewell in line with section 3 of Developing NICE guidelines: the manual. Staff from The National Guideline Alliance undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For a full description of methods see Supplement 1.
Sources of funding/support	The National Guideline Alliance is funded by NICE and hosted by The Royal College of Obstetricians and Gynaecologists
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by The Royal College of Obstetricians and Gynaecologists
Roles of sponsor	NICE funds The National Guideline Alliance to develop guidelines for those working in the NHS, public health, and social care in England
PROSPERO registration number	This protocol has not been registered in PROSPERO

CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; DARE: Database of Abstracts of Reviews of Effects; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HTA: Health Technology Assessment; MID: minimally important difference; NGA: National Guideline Alliance; NICE: National Institute for Health and Care Excellence; RCT: randomised controlled trial

Appendix B – Literature search strategies

Literature search strategies for review question: What tools for clinical review of women (including pain scores) are effective during the first 8 weeks after birth?

Clinical search

The search for this topic was last run on 4th December 2019.

Database: Emcare, Embase, Medline, Medline Ahead of Print and In-Process & Other Non-Indexed Citations – OVID [Multifile]

#	Search
1	perinatal period/ or exp postnatal care/
2	1 use emczd, emcr
3	postpartum period/ or peripartum period/ or postnatal care/
4	3 use ppez
5	(((first time or new) adj mother*) or nullipara* or peri natal* or perinatal* or postbirth or post birth or postdelivery or post delivery or postnatal* or post natal* or postpartum* or post partum* or primipara* or puerpera* or puerperium* or ((after or follow*) adj2 birth*)).ti,ab.
6	or/2,4-5
7	exp constipation/ use emczd, emcr or constipation/ use ppez
8	(colonic inertia or constipat* or dyschezia or obstipation).ti,ab.
9	pain*.hw. use emczd, emcr
10	(discomfort* or pain*).tw.
11	or/7-10
12	checklist/ or clinical assessment tool/ or differential diagnosis/ or mass screening/ or medical assessment/ or nursing assessment/ or pain assessment/ or pain measurement/ or patient assessment/ or "prediction and forecasting"/ or risk assessment/ or screening test/ or "sensitivity and specificity"/
13	12 use emczd, emcr
14	checklist/ or diagnosis, differential/ or exp "sensitivity and specificity"/ or forecasting/ or mass screening/ or nursing assessment/ or pain measurement/ or risk assessment/
15	14 use ppez
16	((chart* or checklist* or indicator* or instrument* or inventory or questionnaire* or scale or scales or score or scores or test or tests or tool or tools) adj5 (colonic inertia or constipat* or dyschezia or obstipation or pain*)).ti,ab.
17	(((assess* or identif* or recogni*) adj5 (chart* or checklist* or indicator* or instrument* or inventory or questionnaire* or scale or scales or score or scores or test or tests or tool or tools)) or (((assess* or identif* or recogni*) adj5 (colonic inertia or constipat* or dyschezia or obstipation or pain*)) and (chart* or checklist* or indicator* or instrument* or inventory or questionnaire* or scale or scales or score or scores or test or tests or tool or tools)) or risk assessment).ti,ab.
18	or/13,15-17
19	(6 and 11 and 18) or (((bristol stool or maternal pain or visual analogue or numeric rating or verbal categorical rating) adj2 (chart* or checklist* or indicator* or instrument* or inventory or questionnaire* or scale or scales or score or scores or test or tests or tool or tools)).ti,ab. and 6 and 11)

#	Search
20	19
21	limit 20 to english language
22	limit 21 to yr="2000 -current"

Database: CDSR, CCRCT [Wiley]

#	Search
#1	mesh descriptor: [postpartum period] this term only
#2	mesh descriptor: [peripartum period] this term only
#3	mesh descriptor: [postnatal care] this term only
#4	((((“first time” or new) adj mother*) or nullipara* or "peri natal*" or perinatal* or postbirth or "post birth" or postdelivery or "post delivery" or postnatal* or "post natal*" or postpartum* or "post partum*" or primipara* or puerpera* or puerperal* or puerperium*)):ti,ab,
#5	#1 or #2 or #3 or #4
#6	mesh descriptor: [constipation] this term only
#7	(("colonic inertia" or constipat* or dyschezia or obstipation)):ti,ab,kw
#8	(pain*):kw
#9	((discomfort* or pain*)):kw
#10	#6 or #7 or #8 or #9
#11	mesh descriptor: [checklist] this term only
#12	mesh descriptor: [checklist] this term only
#13	mesh descriptor: [diagnosis, differential] this term only
#14	mesh descriptor: [sensitivity and specificity] this term only
#15	mesh descriptor: [forecasting] this term only
#16	mesh descriptor: [mass screening] this term only
#17	mesh descriptor: [nursing assessment] this term only
#18	mesh descriptor: [pain measurement] this term only
#19	mesh descriptor: [risk assessment] this term only
#20	(((chart* or checklist* or indicator* or instrument* or inventory or questionnaire* or scale or scales or score or scores or test or tests or tool or tools) near/5 (colonic inertia or constipat* or dyschezia or obstipation or pain*))):ti,ab,kw
#21	((((assess* or identif* or recogni*) near/5 (chart* or checklist* or indicator* or instrument* or inventory or questionnaire* or scale or scales or score or scores or test or tests or tool or tools)) or (((assess* or identif* or recogni*) near/5 ("colonic inertia" or constipat* or dyschezia or obstipation or pain*)) and (chart* or checklist* or indicator* or instrument* or inventory or questionnaire* or scale or scales or score or scores or test or tests or tool or tools)) or "risk assessment")):ti,ab,kw

#	Search
#22	#11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21
#23	#5 and #10 and #22
#24	((("bristol stool" or "maternal pain" or "visual analogue" or "numeric rating" or "verbal categorical rating") near/2 (chart* or checklist* or indicator* or instrument* or inventory or questionnaire* or scale or scales or score or scores or test or tests or tool or tools))):ti,ab,kw
#25	#5 and #10 and #24
#26	#23 or #25
#27	#26 with cochrane library publication date between jan 2000 and dec 2019

Database: DARE, HTA (global) [CRD Web]

#	Search
1	mesh descriptor postpartum period in dare,hta
2	mesh descriptor peripartum period in dare,hta
3	mesh descriptor postnatal care in dare,hta
4	(nullipara* or peri natal* or perinatal* or postbirth or post birth or postdelivery or post delivery or postnatal* or post natal* or postpartum* or post partum* or primipara* or puerpera* or puerperium* or ((after or follow*) near2 birth*)) in dare, hta
5	#1 or #2 or #3 or #4
6	mesh descriptor breast feeding explode all trees in dare,hta
7	mesh descriptor lactation in dare,hta
8	(breastfeed* or breast feed* or breastfed* or breastfeed* or breast fed or breastmilk or breast milk or expressed milk* or lactat* or (nursing next (baby or infant* or mother* or neonate* or newborn*))) in dare, hta
9	#6 or #7 or #8
10	mesh descriptor bottle feeding in dare,hta
11	mesh descriptor infant formula in dare,hta
12	(((bottle or formula or synthetic) near2 (artificial or fed or feed* or infant* or milk*)) or (artificial next (formula or milk)) or bottlefed or bottlefeed or cup feeding or (milk near2 (substitut* or supplement*)) or ((infant or milk or water or glucose or dextrose or formula) next supplement) or formula supplement* or supplement feed or milk feed or ((baby or babies or infant* or neonate* or newborn*) next (formula* or milk)) or formulafeed or formulated or (milk near2 powder*) or hydrolyzed formula* or (((feeding or baby or infant) next bottle*) or infant feeding or bottle nipple* or milk pump*)) in dare, hta
13	#10 or #11 or #12
14	#5 or #9 or #13

Health economic search

The search for this topic was last run on 5th December 2019.

Database: Emcare, Embase, Medline, Medline Ahead of Print and In-Process & Other Non-Indexed Citations – OVID [Multifile]

#	Search
1	puerperium/ or perinatal period/ or postnatal care/

#	Search
2	1 use emczd, emcr
3	postpartum period/ or peripartum period/ or postnatal care/
4	3 use ppez
5	(nullipara* or peri natal* or perinatal* or postbirth or post birth or postdelivery or post delivery or postnatal* or post natal* or postpartum* or post partum* or primipara* or puerpera* or puerperium* or ((after or follow*) adj2 birth*)).ti,ab.
6	or/2,4-5
7	breast feeding/ or breast feeding education/ or lactation/
8	7 use emczd, emcr
9	exp breast feeding/ or lactation/
10	9 use ppez
11	(breastfeed* or breast feed* or breastfed* or breastfeed* or breast fed or breastmilk or breast milk or expressed milk* or lactat* or (nursing adj (baby or infant* or mother* or neonate* or newborn*))).ti,ab.
12	or/8,10-11
13	artificial food/ or bottle feeding/ or infant feeding/
14	13 use emczd, emcr
15	bottle feeding/ or infant formula/
16	15 use ppez
17	(((bottle or formula or synthetic) adj2 (artificial or fed or feed* or infant* or milk*)) or (artificial adj (formula or milk)) or bottlefed or bottlefeed or cup feeding or (milk adj2 (substitut* or supplement*)) or ((infant or milk or water or glucose or dextrose or formula) adj supplement) or formula supplement* or supplement feed or milk feed or ((baby or babies or infant* or neonate* or newborn*) adj (formula* or milk)) or formulafeed or formulated or (milk adj2 powder*) or hydrolyzed formula* or (((feeding or baby or infant) adj bottle*) or infant feeding or bottle nipple* or milk pump*)).ti,ab.
18	or/14,16-17
19	or/6,12,18
20	budget/ or exp economic evaluation/ or exp fee/ or funding/ or exp health care cost/ or health economics/
21	20 use emczd, emcr
22	exp budgets/ or exp "costs and cost analysis"/ or economics/ or exp economics, hospital/ or exp economics, medical/ or economics, nursing/ or economics, pharmaceutical/ or exp "fees and charges"/ or value of life/
23	22 use ppez
24	budget*.ti,ab. or cost*.ti. or (economic* or pharmaco?economic*).ti. or (price* or pricing*).ti,ab. or (cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab. or (financ* or fee or fees).ti,ab. or (value adj2 (money or monetary)).ti,ab.
25	or/21,23-24
26	economic model/ or quality adjusted life year/ or "quality of life index"/
27	(cost-benefit analysis.sh. and (cost-effectiveness ratio* and (perspective* or life expectanc*)).tw.)
28	((quality of life or qol).tw. and cost benefit analysis.sh.)
29	or/26-28 use emczd, emcr
30	models, economic/ or quality-adjusted life years/
31	(cost-benefit analysis.sh. and (cost-effectiveness ratio* and (perspective* or life expectanc*)).tw.)
32	((quality of life or qol).tw. and cost-benefit analysis.sh.)

#	Search
33	or/30-32 use ppez
34	(eq-5d* or eq5d* or eq-5* or eq5* or euroqual* or euro qual* or euroqual 5d* or euro qual 5d* or euro qol* or euroqol*or euro quol* or euroquol* or euro quol5d* or euroquol5d* or eur qol* or eurqol* or eur qol5d* or eurqol5d* or eur?qul* or eur?qul5d* or euro* quality of life or european qol).tw.
35	(euro* adj3 (5 d* or 5d* or 5 dimension* or 5dimension* or 5 domain* or 5domain*)).tw.
36	(hui or hui2 or hui3).tw.
37	(illness state* or health state*).tw.
38	(multiattibute* or multi attribute*).tw.
39	(qaly* or qal or qald* or qale* or qtime* or qwb* or daly).tw.
40	(quality adjusted or quality adjusted life year*).tw.
41	(sf36 or sf 36 or sf thirty six or sf thirtysix).tw.
42	sickness impact profile.sh.
43	(time trade off*1 or time tradeoff*1 or tto or timetradeoff*1).tw.
44	(utilit* adj3 (score*1 or valu* or health* or cost* or measur* or disease* or mean or gain or gains or index*)).tw.
45	utilities.tw.
46	((qol or hrqol or quality of life).tw. or *quality of life/) and ((qol or hrqol* or quality of life) adj2 (change*1 or declin* or decreas* or deteriorat* or effect or effects or high* or impact*1 or impacted or improve* or increas* or low* or reduc* or score or scores or worse)).ab.
47	quality of life.sh. and ((health-related quality of life or (health adj3 status) or ((quality of life or qol) adj3 (chang* or improv*)) or ((quality of life or qol) adj (measure*1 or score*1))).tw. or (quality of life or qol).ti. or ec.fs.)
48	or/29,33-47
49	or/25,48
50	19 and 50
51	limit 50 to english language
52	(animals/ not humans/) or exp animals, laboratory/ or exp animal experimentation/ or exp models, animal/ or exp rodentia/
53	52 use ppez
54	(animal/ not human/) or nonhuman/ or exp animal experiment/ or exp experimental animal/ or animal model/ or exp rodent/
55	54 use emczd, emcr
56	(rat or rats or mouse or mice).ti.
57	or/53,55-56
58	51 not 57

Database: HTA, NHS EED (global) [CRD Web]

#	Search
1	mesh descriptor postpartum period in hta, nhs eed
2	mesh descriptor peripartum period in hta, nhs eed
3	mesh descriptor postnatal care hta, nhs eed
4	(nullipara* or peri natal* or perinatal* or postbirth or post birth or postdelivery or post delivery or postnatal* or post natal* or postpartum* or post partum* or primipara* or puerpera* or puerperium* or ((after or follow*) near2 birth*)) hta, nhs eed
5	#1 or #2 or #3 or #4
6	mesh descriptor breast feeding explode all trees hta, nhs eed

#	Search
7	mesh descriptor lactation hta, nhs eed
8	(breastfeed* or breast feed* or breastfed* or breastfeed* or breast fed or breastmilk or breast milk or expressed milk* or lactat* or (nursing next (baby or infant* or mother* or neonate* or newborn*))) hta, nhs eed
9	#6 or #7 or #8
10	mesh descriptor bottle feeding hta, nhs eed
11	mesh descriptor infant formula hta, nhs eed
12	(((bottle or formula or synthetic) near2 (artificial or fed or feed* or infant* or milk*)) or (artificial next (formula or milk)) or bottlefed or bottlefeed or cup feeding or (milk near2 (substitut* or supplement*)) or ((infant or milk or water or glucose or dextrose or formula) next supplement) or formula supplement* or supplement feed or milk feed or ((baby or babies or infant* or neonate* or newborn*) next (formula* or milk)) or formulafeed or formulated or (milk near2 powder*) or hydrolyzed formula* or (((feeding or baby or infant) next bottle*) or infant feeding or bottle nipple* or milk pump*)) hta, nhs eed
13	#10 or #11 or #12
14	#5 or #9 or #13

Appendix C – Clinical evidence study selection

Clinical study selection for: What tools for clinical review of women (including pain scores) are effective during the first 8 weeks after birth?

Figure 1: Study selection flow chart for RCT database

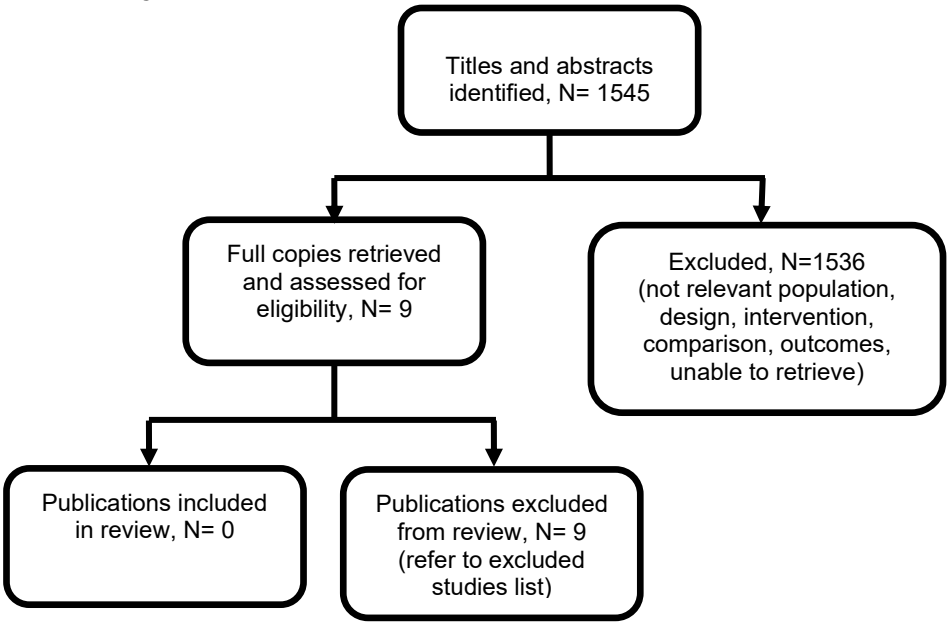
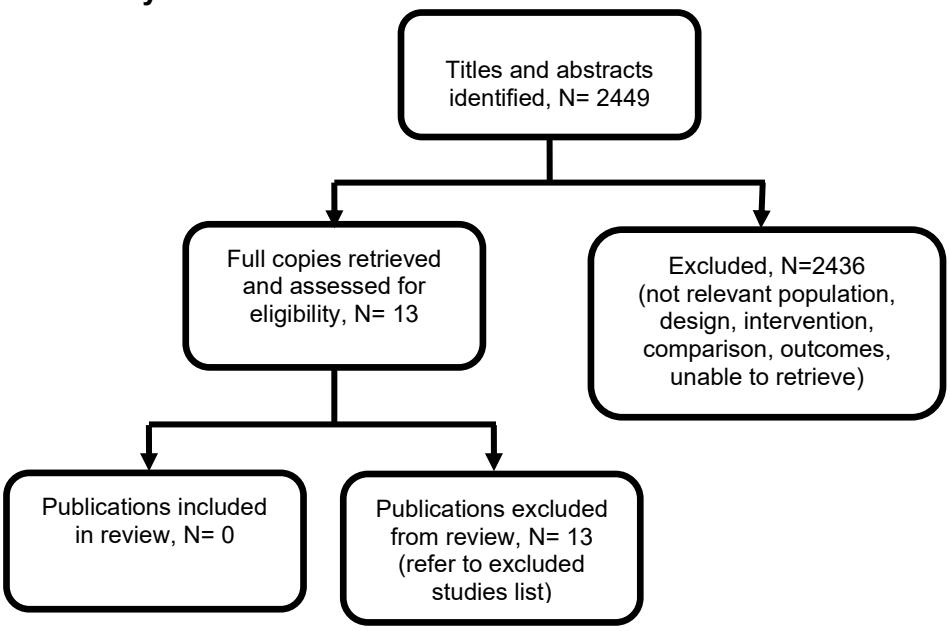


Figure 2: Study selection flow chart for non-RCT database



Appendix D – Clinical evidence tables

Clinical evidence tables for review question: What tools for clinical review of women (including pain scores) are effective during the first 8 weeks after birth?

No evidence was identified which was applicable to this review question.

Appendix E – Forest plots

Forest plots for review question: What tools for clinical review of women (including pain scores) are effective during the first 8 weeks after birth?

No evidence was identified which was applicable to this review question.

Appendix F – GRADE tables

GRADE tables for review question: What tools for clinical review of women (including pain scores) are effective during the first 8 weeks after birth?

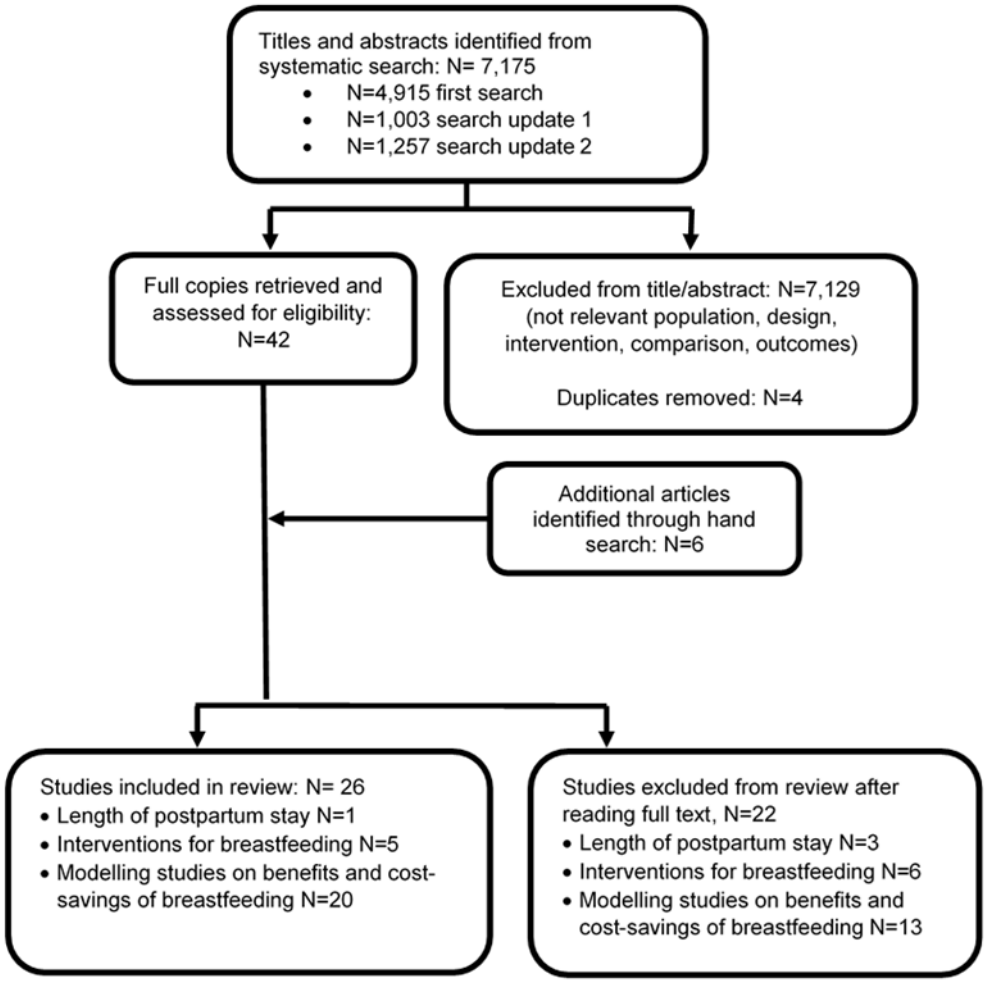
No evidence was identified which was applicable to this review question.

Appendix G – Economic evidence study selection

Economic evidence study selection for review question: What tools for clinical review of women (including pain scores) are effective during the first 8 weeks after birth?

A global health economics search was undertaken for all areas covered in the guideline. Figure 3 shows the flow diagram of the selection process for economic evaluations of postnatal care interventions, including modelling studies on the benefits and cost-savings of breastfeeding.

Figure 3. Flow diagram of selection process for economic evaluations of postnatal care interventions and modelling studies on the benefits and cost-savings of breastfeeding



Appendix H – Economic evidence tables

Economic evidence tables for review question: What tools for clinical review of women (including pain scores) are effective during the first 8 weeks after birth?

No economic evidence was identified which was applicable to this review question.

Appendix I – Economic evidence profiles

Economic evidence profiles for review question: What tools for clinical review of women (including pain scores) are effective during the first 8 weeks after birth?

No economic evidence was identified which was applicable to this review question.

Appendix J – Economic analysis

Economic analysis for review question: What tools for clinical review of women (including pain scores) are effective during the first 8 weeks after birth?

No economic analysis was conducted for this review question.

Appendix K – Excluded studies

Excluded studies for review question: What tools for clinical review of women (including pain scores) are effective during the first 8 weeks after birth?

Clinical studies

Table 3: Excluded studies and reasons for their exclusion (RCT database)

Study	Reason for exclusion
Bick,D.E., Kettle,C., Macdonald,S., Thomas,P.W., Hills,R.K., Ismail,K.M.K., PErineal Assessment and Repair Longitudinal Study (PEARLS): Protocol for a matched pair cluster trial, BMC Pregnancy and Childbirth, 10 , 2010. Article Number, -, 2010	Protocol - delivery of a training package on Perineal assessment.
Brizuela, V., Leslie, H. H., Sharma, J., Langer, A., Tuncalp, O., Measuring quality of care for all women and newborns: how do we know if we are doing it right? A review of facility assessment tools, The Lancet Global Health, 7, e624-e632, 2019	Tool not of interest for review - service assessment and provision of middle and lower income countries.
Gamez, B. H., Habib, A. S., Predicting severity of acute pain after cesarean delivery: A narrative review, Anesthesia and Analgesia, 126, 1606-1614, 2018	Review - contains some studies that assess the validity of pain questionnaires.
Gartner, F. R., de Miranda, E., Rijnders, M. E., Freeman, L. M., Middeldorp, J. M., Bloemenkamp, K. W., Stiggelbout, A. M., van den Akker-van Marle, M. E., Good reliability and validity for a new utility instrument measuring the birth experience, the Labor and Delivery Index, Journal of Clinical EpidemiologyJ Clin Epidemiol, 68, 1184-94, 2015	Study design - Validity of a birth-specific utility questionnaire, called the Labour and Delivery Index (LADY-X).
Gayat,E., Resche-Rigon,M., Morel,O., Rossignol,M., Mantz,J., Nicolas-Robin,A., Nathan-Denizot,N., Lefrant,J.Y., Mercier,F.J., Samain,E., Fargeaudou,Y., Barranger,E., Laisne,M.J., Brechat,P.H., Luton,D., Ouanounou,I., Plaza,P.A., Broche,C., Payen,D., Mebazaa,A., Predictive factors of advanced interventional procedures in a multicentre severe postpartum haemorrhage study, Intensive Care Medicine, 37, 1816-1825, 2011	Study design - Validation of predictive factors that would require advanced interventional procedures.
Grotle, M., Garratt, A. M., Krogstad Jenssen, H., Stuge, B., Reliability and construct validity of self-report questionnaires for patients with pelvic girdle pain, Physical therapy, 92, 111-123, 2012	Study design - Validity of Self-Report Questionnaires for Patients With Pelvic Girdle Pain.
Iliescu, D. G., Dragusin, R., Gheonea, M., Sarbu, M., Novac, M., Tudorache, S., The diagnosis and perinatal management in HELLP syndrome, Obstetrica si Ginecologie, 64, 141-152, 2016	Review on HELLP syndrome.
Petrou, S., Morrell, J., Spiby, H., Assessing the empirical validity of alternative multi-attribute utility measures in the maternity context, Health and Quality of Life Outcomes, 7 (no pagination), 2009	Study design - Economic analysis of an RCT that randomised women to receive extra postnatal support from a community support worker.
Yen, T. W., Payne, B., Qu, Z., Hutcheon, J. A., Lee, T., Magee, L. A., Walters, B. N., von Dadelszen, P., Piers Study Group, Using clinical symptoms to predict adverse maternal and	Study design - calculating relative risks of symptoms that may indicate pre-eclampsia.

perinatal outcomes in women with preeclampsia: data from the PIERS (Pre-eclampsia Integrated Estimate of RiSk) study, Journal of Obstetrics & Gynaecology Canada: JOGCJ Obstet Gynaecol Can, 33, 803-809, 2011	

HELLP: haemolysis (H), elevated liver enzymes (EL), and low platelets (LP); LADY-X: labour and delivery index; RCT: randomised controlled trial.

Table 4: Excluded studies and reasons for their exclusion (non-RCT database)

Study	Reason for exclusion
Cano-Climent, A., Oliver-Roig, A., Cabrero-Garcia, J., de Vries, J., Richart-Martinez, M., The Spanish version of the Fatigue Assessment Scale: Reliability and validity assessment in postpartum women, PeerJ, 2017 (9) (no pagination), 2017	Study design - Validity of the Spanish translated version of the Fatigue Assessment Scale used in postpartum women.
Chang, S. R., Chen, K. H., Lee, C. N., Shyu, M. K., Lin, M. I., Lin, W. A., Relationships between perineal pain and postpartum depressive symptoms: A prospective cohort study, International journal of nursing studies, 59, 68-78, 2016	Study design - Linking pain (incl perineal pain to postnatal depression).
Eisenach,J.C., Pan,P.H., Smiley,R., Lavand'homme,P., Landau,R., Houle,T.T., Severity of acute pain after childbirth, but not type of delivery, predicts persistent pain and postpartum depression, Pain, 140, 87-94, 2008	Study design - Predicting persistent pain and postpartum depression from postpartum pain scores.
Hsieh, C. H., Chen, C. L., Han, T. J., Lin, P. J., Chiu, H. C., Factors Influencing Postpartum Fatigue in Vaginal-Birth Women: Testing a Path Model, The journal of nursing research : JNR, 26, 332-339, 2018	Study design - Creating a model that predicts postpartum fatigue.
Jardri,R., Maron,M., Delion,P., Thomas,P., Pain as a confounding factor in postnatal depression screening, Journal of Psychosomatic Obstetrics and Gynecology, 31, 252-255, 2010	Study design - Predicting postnatal depression from pain measurements.
Lagaert, L., Weyers, S., Van Kerrebroeck, H., Elaut, E., Postpartum dyspareunia and sexual functioning: a prospective cohort study, European Journal of Contraception and Reproductive Health Care, 22, 200-206, 2017	Study design -Assessing sexual function and prevalence of postpartum dyspareunia, pre-birth, 6 weeks and 6 months post-birth.
Lopez-Lapeyrere, C., Serna-Gomez, N., Hernandez-Lopez, A. B., Perez-Garcia, M. F., Tejeda-Esteban, A., Solis-Munoz, M., The development and validation of a new postpartum sexual function and dyspareunia assessment tool: The Carol Scale, Midwifery, 58, 27-36, 2018	Study design – non comparative study
Mens, J. M. A., Vleeming, A., Snijders, C. J., Koes, B. W., Stam, H. J., Validity of the active straight leg raise test for measuring disease severity in patients with posterior pelvic pain after pregnancy, Spine, 27, 196-200, 2002	Study design - Validation of the straight leg raise test for posterior pelvic pain after pregnancy.
Persico, G., Vergani, P., Cestaro, C., Grandolfo, M., Nespoli, A., Assessment of postpartum perineal pain after vaginal delivery: Prevalence, severity and determinants. A prospective observational study, Minerva Ginecologica, 65, 669-678, 2013	Study design - Prevalence of perineal pain postpartum.
Rejano-Campo, M., Ferrer-Pena, R., Urraca-Gesto, M. A., Gallego-Izquierdo, T., Pecos-Martin, D., Stuge, B., Plaza-Manzano, G., Transcultural adaptation and psychometric validation of a Spanish-language version of the "Pelvic Girdle Questionnaire", Health & Quality of Life Outcomes, 15, 30, 2017	Study design - Validation of translation to Spanish of the pelvic girdle questionnaire.
Smith,L.F.P., Postnatal care: Development of a psychometric multidimensional satisfaction questionnaire (the WOMBPNSQ) to assess women's views, British Journal of General Practice, 61, e628-e637, 2011	Study design - Development of the Women's views of Birth Postnatal Satisfaction Questionnaire.

Stomp-van den Berg, S. G., Hendriksen, I. J., Bruinvels, D. J., Twisk, J. W., van Mechelen, W., van Poppel, M. N., Predictors for postpartum pelvic girdle pain in working women: the Mom@Work cohort study, Pain, 153, 2370-9, 2012	Study design - Predictors for postpartum pelvic girdle pain.
Webb, D. A., Bloch, J. R., Coyne, J. C., Chung, E. K., Bennett, I. M., Culhane, J. F., Postpartum physical symptoms in new mothers: their relationship to functional limitations and emotional well-being, Birth: Issues in Perinatal Care, 35, 179-187, 2008	Study Design - Linking emotional health to physical problems in the postpartum period.

Economic studies

No economic evidence was identified for this review.

Appendix L – Research recommendations

Research recommendations for review question: What tools for clinical review of women (including pain scores) are effective during the first 8 weeks after birth?

Research question: What tools for the clinical review of women are effective in the first eight weeks after birth?

Why this is important

Whilst low, the majority of maternal mortality in the UK occurs in the postnatal period. In addition, women's surveys relating to their NHS postnatal care have consistently identified poorer experiences and unmet needs. The postnatal period thus represents a clinically high-risk period for some. There is therefore a need to identify validated tools of postnatal review (including pain score, fatigue, trauma, psychosexual concerns) which support accurate assessment during this period.

Table 8: Research recommendation rationale

Research question	
Why is this needed	
Importance to 'patients' or the population	Poor postnatal outcomes and experiences slow women's recovery from childbirth and negatively impacts their quality of life and bonding and attachment with their baby.
Relevance to NICE guidance	There is limited evidence regarding validated clinical assessment tools, which take into account the uniqueness of the postnatal period.
Relevance to the NHS	Poor postnatal outcomes and experiences negatively impact the use of NHS healthcare resources by the mother and baby, and in some circumstances the father or partner.
National priorities	The NHS Five Year Forward View for maternity care, 'Better Births', calls for better postnatal care to significantly impact the life chances and wellbeing of the woman, baby and family. The NHS Long Term Plan aims to accelerate action to achieve 50% reduction in maternal mortality.
Current evidence base	No evidence could be identified for tools for clinical review specific for women in the first eight weeks after birth
Equality	Note- maternal mortality figures are reported to be higher in Black, Asian and Minority Ethnic (BAME) women.
Feasibility	Yes, given the number of births per year
Other comments	-

Table 9: Research recommendation modified PICO table

Criterion	Explanation
Population	Women in the first 8 weeks after birth
Intervention	Clinical review tools (including pain score, fatigue, trauma, psychosexual concerns)
Comparator	Standard care
Outcomes	• Mortality • Unplanned attendance to health services including admissions

Criterion	Explanation
	• Depression • Anxiety • Post-traumatic stress disorder (PTSD) • Pain score • Quality of life • Bonding and attachment with the baby • Psychosexual problems • Health economics
Study design	RCT
Timeframe	The research should take place in time to inform future updates of this NICE guideline.
Additional information	-

RCT: randomised controlled trial