National Institute for Health and Care Excellence

Intrapartum care

[Q] Technical appendices for the effects and safety of water immersion during the second stage of labour

NICE guideline NG235

Technical data underpinning evidence review Q

August 2025

Draft for consultation

Copyright					
© NICE 2025. All rights reserved. Subject to Notice of rights.					

Contents

Appendix A - Review protocols	4
Review protocol for effectiveness review: What are the effects and safe	∍ty
of water immersion during the second stage of labour in healthy wome	n
with uncomplicated singleton pregnancies at term and their babies?	4
Economic review protocol	4
Appendix B - Literature search strategies	7
Background and development	7
Search limits and other restrictions	8
Search filters and classifiers	9
Key decisions	9
Effectiveness searches	9
Cost-effectiveness searches	. 19
Appendix C - Study selection – effectiveness evidence	.25
Appendix D - Effectiveness evidence tables	.26
Appendix E - Forest plots	.48
Appendix F - GRADE summary	.49
Appendix G - Economic evidence study selection	.61
Appendix H - Economic evidence tables	.62
Appendix I - Excluded studies	.65
Effectiveness	.65
Economic	.78
Appendix J - Methods	.80
Appendix K - Research recommendations	.85

1 Appendix A - Review protocols

- 2 Review protocol for effectiveness review: What are the effects and
- 3 safety of water immersion during the second stage of labour in
- 4 healthy women with uncomplicated singleton pregnancies at term
- 5 and their babies?
- 6 The full protocol can be found at Project documents | Intrapartum Care -
- 7 Water birth: second stage of labour | Guidance | NICE

8 Economic review protocol

Review question	Review question 1 – economic evidence
Objective	To identify economic studies relevant to any of the guideline review questions
Inclusion criteria	 Populations, interventions and comparators must be as specified in the clinical review protocol.
	 Relevant comparative economic study design: cost—utility analysis, cost—effectiveness analysis, cost—consequences analysis, comparative cost analysis
	Decision analytic model-based or within-trial economic analyses
	OECD countries (except USA)
	Healthcare and personal social services cost perspective
	 Non-comparative costing studies (such as econometric, efficiency, simulation, micro-costing and resource use, and time-series)
	 Studies published from 2005 – this cut off has been applied to restrict the review to more recent studies which will have more applicable resource use and costs. From 2005 has been chosen to align with the effectiveness protocol which starts from 2005 to ensure no relevant papers are missed.
	High-quality studies in line with the NICE reference case (recent UK NHS/PSS cost-utility analyses using the QALY as the measure of outcome) are the most applicable to NICE decision making. Not all studies meeting the inclusion criteria will therefore necessarily be used in decision-making - see Review strategy below for details.
Exclusion criteria	 Conference posters or abstract only studies – these do not provide sufficient information for quality assessment.
	 Studies published before 2005 – this cut off has been applied to restrict the review to more recent studies which will have more applicable resource use and costs.
	 Studies from non-OECD countries or the USA – these are considered unlikely to be applicable to the UK NHS setting due to substantial differences in healthcare delivery and unit costs.
	 Economic analyses utilising effectiveness data from studies with a mirror- image design and studies that recruited participants retrospectively, due to their lower methodological quality.

- Analyses based on clinical evidence that is not included in the clinical evidence review
- Within-trial economic analyses based on studies that have been excluded from the clinical review
- Economic model analyses based exclusively on studies that have been excluded from the clinical review
- Non-comparative economic analyses including cost-of-illness studies.
- Letters, editorials or commentaries, study protocols or reviews of economic evaluations (recent reviews will be ordered and the bibliographies will be checked for relevant individual economic studies, which will then be ordered and checked for eligibility).
- Non-English language papers.
- Studies considering exclusively intervention costs, e.g. medicine acquisition costs, without considering wider healthcare costs associated with the management of the second stage of labour.
- Studies comparing costs of branded vs generic forms of the same medicine.
- Studies only focussing on productivity losses or gains.

Search strategy

An economic study search will be undertaken covering this review question using guideline population-specific terms and a health economic study filter. For search details see appendix B below.

The following databases will be searched:

- Centre for Reviews and Dissemination NHS Economic Evaluations Database (NHS EED) – all years (closed to new records April 2015)
- Centre for Reviews and Dissemination Health Technology Assessment database – all years (closed to new records March 2018)
- International HTA database (INAHTA) all years
- Medline and Embase from 2014 (due to NHS EED closure)

Review strategy

- Studies meeting the inclusion and exclusion criteria will be assessed for applicability and methodological limitations using the NICE economic evaluation checklist in appendix H of <u>Developing NICE quidelines: the</u> manual.
- The NICE economic evaluation checklist assesses:
 - Applicability to the NICE guideline decision making context with consideration of the <u>NICE reference case relevant to the guideline</u>.
 Recent UK studies that use the NICE reference case methods are the most applicable when considering cost effectiveness.
 - Methodological limitations.
- The aim is to present the best available economic evidence to inform committee decision-making in the context of the guideline, the current UK NHS setting and NICE methods. Therefore, the health economist may not present all studies that meet inclusion criteria. If recent high quality, UK cost-utility analyses are available for a question, it is often not deemed informative to present studies that are less applicable or lower quality such as older UK analyses or analyses from other countries. A similar principle is deemed to apply more generally when considering applicability and methodological limitations. Some specific examples are given below:
 - If multiple versions of a model are available for the UK and other countries it is usually reasonable to only present the UK version.

- If multiple versions of the same UK model are available, it is usually reasonable to present only the most recent.
- If there has been a NICE MTA or guideline model that informs current NHS practice it is usually reasonable not to present older studies, unless they address a different subpopulation or other specific issue.
- If a UK model that includes all interventions in the decision space is available it may be reasonable not to present studies that only include individual or fewer interventions, if the analysis is sufficiently applicable and of good methodological quality.
- Quality and relevance of effectiveness data used in the economic analysis: the more closely the clinical effectiveness data used in the economic analysis match with the outcomes of the studies included in the clinical review the more useful the analysis will be for decision-making in the guideline.
- Hierarchy of economic evaluation evidence based on quality assessment
 - 'Directly applicable' and 'Minor limitations' (only recent UK CUAs can get this rating). Usually presented and used in decision-making.
 - Directly or partially applicable combined with minor or potentially serious limitations (other than 1). Discretion over whether these are presented and used in decision-making, depending on the availability of more relevant evidence.
 - 'Not applicable' or 'Very serious limitations'. Typically, not presented and not used in decision-making.

The health economist will make a decision based on the relative applicability and quality of the available evidence for each question, in discussion with the guideline committee if required. All decisions will be transparently reported in the evidence report. Studies that are presented to the committee and used in decision-making when formulating recommendations will be included in the summary tables and will have an evidence extraction. Other studies may not be presented to the committee in detail but will be listed, with the reason for not being presented to the committee and thus not used in decision-making being provided. Committee members can review and query the decision not to present studies with the health economist and will be provided with full details of these studies where requested.

1

1 Appendix B - Literature search strategies

2 Background and development

- 3 Search design and peer review
- 4 A NICE Senior Information Specialist (SIS) conducted the literature searches
- 5 for the evidence review.
- 6 The principal search strategies were developed in MEDLINE (Ovid interface)
- 7 and adapted, as appropriate, for use in the other sources listed in the
- 8 protocol, taking into account their size, search functionality and subject
- 9 coverage.
- 10 The MEDLINE strategies below were quality assured (QA) by a trained NICE
- 11 SIS. All translated search strategies were peer reviewed by another SIS to
- 12 ensure their accuracy. Both procedures were adapted from the Peer Review
- of Electronic Search Strategies Guideline Statement (for further details see:
- 14 McGowan J et al. PRESS 2015 Guideline Statement. Journal of Clinical
- 15 *Epidemiology*, 75, 40-46).
- 16 This search report is based on the requirements of the PRISMA Statement for
- 17 Reporting Literature Searches in Systematic Reviews (for further details see:
- 18 Rethlefsen M et al. PRISMA-S. Systematic Reviews, 10(1), 39).

19 Review management

- 20 The search results were managed in EPPI-Reviewer v5. Duplicates were removed in
- 21 EPPI-R5 using a two-step process. First, automated deduplication is performed using
- 22 a high-value algorithm. Second, manual deduplication is used to assess "low-
- 23 probability" matches. All decisions made for the review can be accessed via the
- 24 deduplication history.

25 **Prior work**

- The original review was undertaken in the guideline CG190 Intrapartum care for
- 27 healthy women and babies. No search histories or last searched dates are available
- 28 from the earlier review.
- 29 Nine key papers were identified:

- 1 Three papers were included references from CG190.
- 2 Five papers were identified from NICE surveillance review.
- 3 One paper was identified from a guideline committee member.
- 4 Search limits and other restrictions
- 5 Formats
- 6 Limits were applied in adherence to standard NICE practice (as set out in the
- 7 <u>Identifying the evidence chapter</u> of the manual) and the eligibility criteria listed
- 8 in the review protocol to exclude:
- 9 Animal studies
- Editorials, letters, news items and commentaries
- Conference abstracts and posters
- Registry entries for ongoing clinical trials or those that contain no
- results
- Theses and dissertations
- Papers not published in the English language.
- 16 The limit to remove animal studies in the searches was the standard NICE
- practice, which has been adapted from:
- 18 Dickersin K, Scherer R & Lefebvre C. (1994) Systematic reviews: identifying
- 19 <u>relevant studies for systematic reviews</u>. *BMJ*, 309(6964), 1286.
- 20 Date limits
- A date limit of 2005 to 2025 was applied, as stated in the review protocol.
- 22 The original review included 2 papers from 2004 and one from 1999. To
- 23 ensure no relevant papers are missed, it was decided that the search would
- 24 start from 2005.

1 Search filters and classifiers

- 2 Cost effectiveness searches
- 3 The following search filters were applied to the search strategies in MEDLINE
- 4 and Embase to identify cost-effectiveness studies:
- 5 Glanville J et al. (2009) <u>Development and Testing of Search Filters to Identify</u>
- 6 <u>Economic Evaluations in MEDLINE and EMBASE</u>. Alberta: Canadian Agency
- 7 for Drugs and Technologies in Health (CADTH)
- 8 Note: Several modifications have been made to these filters over the years
- 9 that are standard NICE practice.

10 Key decisions

- 11 The search strategy was developed to find evidence on for the specified
- population and intervention in the review protocol. The population focuses on
- the second stage of labour and does not include pregnancy or other stages of
- 14 labour or birth.

15 Effectiveness searches

Database results

16

Databases	Date searched	Database platform	Database segment or version	No. of results downloaded
Cochrane Central Register of Controlled Trials (CENTRAL)	21/05/2025	Wiley	Issue 4 of 12, April 2025	75
Cochrane Database of Systematic Reviews (CDSR)	21/05/2025	Wiley	Issue 5 of 12, May 2025	9
Cumulative Index to Nursing and Allied Health Literature (CINAHL)	21/05/2025	EBSCOhost		468

Intrapartum care – Water birth: second stage of labour: evidence review for water immersion during the second stage of labour DRAFT (August 2025)

Page 9 of 85

Embase	21/05/2025	Ovid	1996 to	868
			2025 May	
			20	
Emcare	21/05/2025	Ovid	1995 to	738
			2025	
			Week 20	
Epistemonikos	21/05/2025	https://www.epistemonikos.org/		295
MEDLINE ALL	21/05/2025	Ovid		545

Additional search methods

1

Additional methods	Date searched	No. of results downloaded
Forward citation searching (of 3 included references from CG190) with WOS	21/05/2025	90
Forward citation searching of (3 included references from CG190) with Google Scholar	21/05/2025	101
Reference list checking (of studies from NICE surveillance review) with WOS	21/05/2025	128

2 Search strategy history

3 Database name: Cochrane Database of Systematic Reviews (CDSR)

Searches				
ID	Search			
#1	MeSH descriptor: [Labor Stage, Second] this term only			
#2	MeSH descriptor: [Labor, Obstetric] this term only			
#3	MeSH descriptor: [Delivery, Obstetric] explode all trees			
#4	MeSH descriptor: [Parturition] explode all trees			
#5	MeSH descriptor: [Perinatal Care] this term only			
#6 labor o	#6 ((during or give or giving or push*) near/5 (birth* or childbirth* or deliver* or labor or labour or labored or laboured or laboring or labouring)):ti,ab,kw			
#7 delive	#7 ((second or 2nd) near/1 (phase* or stage*) near/3 (birth* or childbirth* or deliver* or labor or labour or labored or laboured or laboring or labouring)):ti,ab,kw			
,	#8 (("phase two" or "phase 2" or "stage two" or "stage 2" or "phase II" or "stage II") near/3 (birth* or childbirth* or deliver* or labor or labour or labored or labouring or labouring)):ti,ab,kw			
#9 peripa	#9 (intrapartu* or partu* or perinat* or "peri natal" or "peri natally" or peripartu*):ti,ab,kw			
#10	{or #1-#9}			
#11	MeSH descriptor: [Water] this term only			
#12	MeSH descriptor: [Immersion] this term only			
#13	MeSH descriptor: [Hydrotherapy] this term only			
#14	waterbirth*:ti,ab,kw			

- #15 ((immers* or water* or underwater*) near/3 (birth* or childbirth* or deliver* or labor or labour or laboured or laboured or labouring or labouring)):ti,ab,kw
- #16 ((bath* or pool or pools or tub or tubs) near/3 (birth* or childbirth* or deliver* or labor or labour or labored or laboured or laboring or labouring)):ti,ab,kw
- #17 (hydrotherap* or (hydro next therap*)):ti,ab,kw
- #18 {or #11-#17}
- #19 #10 and #18 with Cochrane Library publication date Between Jan 2005 and May 2025, in Cochrane Reviews, Cochrane Protocols

1 Database name: Cochrane Central Register of Controlled Trials

2 (CENTRAL)

Searches				
ID	Search			
#1	MeSH descriptor: [Labor Stage, Second] this term only			
#2	MeSH descriptor: [Labor, Obstetric] this term only			
#3	MeSH descriptor: [Delivery, Obstetric] explode all trees			
#4	MeSH descriptor: [Parturition] explode all trees			
#5	MeSH descriptor: [Perinatal Care] this term only			
#6 labor o	((during or give or giving or push*) near/5 (birth* or childbirth* or deliver* or labour or labored or laboured or laboring or labouring)):ti,ab,kw			
#7 deliver	((second or 2nd) near/1 (phase* or stage*) near/3 (birth* or childbirth* or or labor or labour or labored or laboured or laboring or labouring)):ti,ab,kw			
,	(("phase two" or "phase 2" or "stage two" or "stage 2" or "phase II" or "stage ar/3 (birth* or childbirth* or deliver* or labor or labour or labored or laboured or labouring)):ti,ab,kw			
#9 peripar	(intrapartu* or partu* or perinat* or peri natal or peri natally or ripartu*):ti,ab,kw			
#10	{or #1-#9}			
#11	MeSH descriptor: [Water] this term only			
#12	MeSH descriptor: [Immersion] this term only			
#13	MeSH descriptor: [Hydrotherapy] this term only			
#14	waterbirth*:ti,ab,kw			
#15 ((immers* or water* or underwater*) near/3 (birth* or childbirth* or deliver* or labor or labour or labored or laboured or laboring or labouring)):ti,ab,kw				
#16 or labo	((bath* or pool or pools or tub or tubs) near/3 (birth* or childbirth* or deliver* or labour or labored or laboured or laboring or labouring)):ti,ab,kw			
#17	(hydrotherap* or (hydro next therap*)):ti,ab,kw			
#18	{or #11-#17}			
#19	#10 and #18			
#20 or trials	#20 ((clinicaltrials or trialsearch* or trial-registry or trials-registry or clinicalstudies or trialsregister* or trialregister* or trial-number* or studyregister* or studyregister*			

or controlled-trials-com or current-controlled-trial or AMCTR or ANZCTR or

ChiCTR* or CRiS or CTIS or CTRI* or DRKS* or EU-CTR* or EUCTR* or EUDRACT* or ICTRP or IRCT* or JAPIC* or JMCTR* or JRCT or ISRCTN* or LBCTR* or NTR* or ReBec* or REPEC* or RPCEC* or SLCTR or TCTR* or UMIN*):so or (ctgov or ictrp)):an

#21 #19 not #20

#22 "conference":pt

#23 #21 not #22 with Publication Year from 2005 to 2025, in Trials

1 Database name: CINAHL

Searches

- # Query
- S24 S22 AND S23
- S23 DT 20050101-20250521
- S22 S20 AND S21
- S21 LA English
- S20 S11 AND S19
- S19 S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18
- S18 XB (hydrotherap* or hydro therap*)
- S17 XB ((bath* or pool or pools or tub or tubs) N3 (birth* or childbirth* or deliver* or labo#r*))
- S16 XB ((immers* or water* or underwater*) N3 (birth* or childbirth* or deliver* or labo#r*))
- S15 (MH "Hydrotherapy")
- S14 (MH "Immersion")
- S13 (MH "Water Birth")
- S12 (MH "Water")
- S11 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10
- S10 XB (intrapartu* or partu* or perinat* or peri nat* or peripartu*)
- S9 ((phase two or phase 2 or stage two or stage 2 or phase II or stage II) N3 (birth* or childbirth* or deliver* or labo#r*))
- S8 XB ((second or 2nd) N1 (phase* or stage*) N3 (birth* or childbirth* or deliver* or labo#r*))
- S7 XB ((during or give or giving or push*) N5 (birth* or childbirth* or deliver* or labo#r*))
- S6 (MH "Perinatal Care")
- S5 (MH "Intrapartum Care+")
- S4 (MH "Labor")
- S3 (MH "Obstetric Care")
- S2 (MH "Delivery, Obstetric+")
- S1 (MH "Labor Stage, Second")

1 Database name: EMBASE

32

33

or/26-32

Searches # Searches 1 labor stage 2/ 2 labor/ 3 birth/ or childbirth/ 4 exp obstetric delivery/ 5 term birth/ 6 intrapartum care/ 7 perinatal care/ or perinatal period/ ((during or give or giving or push*) adj5 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf. ((second or 2nd) adj1 (phase* or stage*) adj3 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf. ((phase two or phase 2 or stage two or stage 2 or phase II or stage II) adj3 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf. 11 (intrapartu* or partu* or perinat* or peri nat* or peripartu*).tw,kf. 12 or/1-11 13 water/ 14 water birth/ 15 water immersion labor pool/ 16 water immersion/ 17 immersion/ 18 birthing pool/ 19 hydrotherapy/ 20 ((immers* or water* or underwater*) adj3 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf. ((bath* or pool? or tub?) adj3 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf. 22 (hydrotherap* or hydro therap*).tw,kf. 23 or/13-22 12 and 23 24 25 limit 24 to english language 26 animal/ 27 nonhuman/ 28 exp Animal Experiment/ 29 exp Experimental Animal/ 30 animal model/ 31 exp Rodent/

(rat or rats or mouse or mice or rodent*).ti.

Searc	Searches			
34	33 not human/			
35	25 not 34			
36	letter.pt. or letter/			
37	note.pt.			
38	editorial.pt.			
39	(letter or comment*).ti.			
40	or/36-39			
41	randomized controlled trial/ or random*.ti,ab.			
42	40 not 41			
43	35 not 42			
44	43 not clinical trial.pt.			
45	44 not conference*.db,pt,su.			
46	limit 45 to dc=20050101-20250521			
47	limit 45 to dd=20050101-20250521			
48	46 or 47			

1 Database name: EMCARE

Searches				
#	Searches			
1	labor stage 2/			
2	labor/			
3	birth/ or childbirth/			
4	exp obstetric delivery/			
5	term birth/			
6	intrapartum care/			
7	perinatal care/ or perinatal period/			
8 labo?ı	8 ((during or give or giving or push*) adj5 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf.			
9 ((second or 2nd) adj1 (phase* or stage*) adj3 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf.				
10 (birth*	((phase two or phase 2 or stage two or stage 2 or phase II or stage II) adj3 or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf.			
11	(intrapartu* or partu* or perinat* or peri nat* or peripartu*).tw,kf.			
12	or/1-11			
13	water/			
14	water birth/			
15	water immersion labor pool/			
16	water immersion/			
17	immersion/			
18	birthing pool/			

- 19 hydrotherapy/
- 20 ((immers* or water* or underwater*) adj3 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf.
- 21 ((bath* or pool? or tub?) adj3 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf.
- 22 (hydrotherap* or hydro therap*).tw,kf.
- 23 or/13-22
- 24 12 and 23
- 25 limit 24 to english language
- 26 animal/
- 27 nonhuman/
- 28 exp Animal Experiment/
- 29 exp Experimental Animal/
- 30 animal model/
- 31 exp Rodent/
- 32 (rat or rats or mouse or mice or rodent*).ti.
- 33 or/26-32
- 34 33 not human/
- 35 25 not 34
- 36 letter.pt. or letter/
- 37 note.pt.
- 38 editorial.pt.
- 39 (letter or comment*).ti.
- 40 or/36-39
- 41 randomized controlled trial/ or random*.ti,ab.
- 42 40 not 41
- 43 35 not 42
- 44 43 not clinical trial.pt.
- 45 44 not conference*.pt,su,so.
- 46 limit 45 to dc=20050101-20250521
- 47 limit 45 to dd=20050101-20250521
- 48 46 or 47

2 Database: Epistemonikos

Searches

Title/Abstract: ((during or give or giving or push*) AND (birth* or childbirth* or deliver* or labor or labors or labour or labours or labored or laboring or labouring))

OR

1

Intrapartum care – Water birth: second stage of labour: evidence review for water immersion during the second stage of labour DRAFT (August 2025) Page 15 of 85

Title/Abstract: (("phase two" or "phase 2" or "stage two" or "stage 2" or "phase ii" or "stage ii") or AND (birth* or childbirth* or deliver* or labor or labors or labour or laboured or laboured or laboring or labouring))

OR

Title/Abstract: ((second or 2nd) AND (phase* or stage*) AND (birth* or childbirth* or deliver* or labor or labors or labour or labours or labored or laboring or labouring))

OR

Title/Abstract: (intrapartu* or partu* or perinat* or "peri natal" or "peri natally" or peripartu*)

AND

Title/Abstract: (waterbirth* OR ((bath* or immers* or pool or pools or tub or tubs or water* or underwater*) AND (birth* or childbirth* or deliver* or labor or labors or labour or laboured or laboured or laboring or labouring)) OR (hydrotherap* or "hydro therapy" or "hydro therapies"))

Limit year to 2005 - 2025

1

2 Database: MEDLINE ALL

Searches

- # Searches
- 1 Labor Stage, Second/
- 2 Labor, Obstetric/
- 3 exp Delivery, Obstetric/
- 4 exp Parturition/
- 5 Perinatal Care/
- 6 ((during or give or giving or push*) adj5 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf.
- 7 ((second or 2nd) adj1 (phase* or stage*) adj3 (birth* or childbirth* or deliver* or labo?red or labo?ring)).tw,kf.
- 8 ((phase two or phase 2 or stage two or stage 2 or phase II or stage II) adj3 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf.
- 9 (intrapartu* or partu* or perinat* or peri nat* or peripartu*).tw,kf.
- 10 or/1-9
- 11 Water/
- 12 Immersion/
- 13 Hydrotherapy/
- 14 waterbirth*.tw,kf.
- 15 ((immers* or water* or underwater*) adj3 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf.
- 16 ((bath* or pool? or tub?) adj3 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf.

Sear	Searches			
17	(hydrotherap* or hydro therap*).tw,kf.			
18	or/11-17			
19	10 and 18			
20	limit 19 to english language			
21	animals/			
22	exp Animals, Laboratory/			
23	exp Animal Experimentation/			
24	exp Models, Animal/			
25	exp Rodentia/			
26	(rat or rats or mouse or mice or rodent*).ti.			
27	or/21-26			
28	27 not humans/			
29	20 not 28			
30	letter/			
31	editorial/			
32	news/			
33	exp historical article/			
34	Anecdotes as Topic/			
35	comment/			
36	(letter or comment*).ti.			
37	or/30-36			
38	randomized controlled trial/ or random*.ti,ab.			
39	37 not 38			
40	29 not 39			
41	40 not overall.pt.			
42	limit 41 to ed=20050101-20250521			
43	limit 41 to dt=20050101-20250521			
44	42 or 43			

2 Additional search methods

1

3 Forward citation searching

Date of search	21/05/2025
How the seed references were identified	Included references from NICE CG190
Sources and tools used	Web of Science
	Google Scholar

How results were managed and selected	A title search was done for all seed references and the selected results added to a single marked list and exported in ris format. Pre-2005 references were removed from the marked list in WOS and Google Scholar before downloading the results. In Google Scholar other criteria not conforming to the protocol were not added to the marked list, e.g. non-English articles, theses, etc.
No. of results	191
List of seed references used	Cluett ER, Nikodem VC, McCandlish RE, Burns EE. Cochrane Database of Systematic Reviews. 2. Oxford: Update Software; 2004. Immersion in water in pregnancy, labour and birth Woodward J, Kelly SM. A pilot study for a randomised controlled trial of waterbirth versus land birth. BJOG: an international journal of obstetrics & gynaecology. 2004;111(6):537–45 Gilbert RE, Tookey PA. Perinatal
	mortality and morbidity among babies delivered in water: surveillance study and postal survey. British Medical Journal. 1999;319(7208):483–7

1 Reference list searching

Date of search	21/05/2025
How the seed references were identified	NICE surveillance review
Sources and tools used	Web of Science
How results were managed and selected	A title search was done for all seed references and the selected results added to a single marked list and exported in ris format. Excluded those not conforming to protocol criteria, e.g. non-English, conference abstracts, articles about methodology, etc

No. of results	128
List of seed references used	Cluett, E et al (2018) Immersion in water during labour and birth Cochrane Database of Systematic Reviews Issue 5. Art. No.: CD000111
	Sanders, J et al (2024) Maternal and neonatal outcomes among spontaneous vaginal births occurring in or out of water following intrapartum water immersion BJOG 131(12): 1650–1659
	McKinney, J et al (2024) Water birth: a systematic review and meta-analysis of maternal and neonatal outcomes Am J Obstet Gynecol. 230(3S):S961-S979.e33
	Bovbjerg, M et al (2022) Maternal and neonatal outcomes following waterbirth: a cohort study of 17 530 waterbirths and 17 530 propensity score-matched land births BJOG 129(6):950-958
	Burns, E et al (2022) Systematic review and meta-analysis to examine intrapartum interventions, and maternal and neonatal outcomes following immersion in water during labour and waterbirth BMJ Open 12:e056517

1 Cost-effectiveness searches

Database results

2

Databases	Date searched	Database platform	Database segment or version	No. of results downloaded
Embase	21/05/2025	Ovid	1996 to 2025 May 20	33
International HTA Database	21/05/2025	https://database.inahta.org/		11
MEDLINE ALL	21/05/2025	Ovid		14

1 Search strategy history

2 Database name: EMBASE

Sear	Searches		
#	Searches		
1	labor stage 2/		
2	labor/		
3	birth/ or childbirth/		
4	exp obstetric delivery/		
5	term birth/		
6	intrapartum care/		
7	perinatal care/ or perinatal period/		
8 labo?	((during or give or giving or push*) adj5 (birth* or childbirth* or deliver* or r? or labo?red or labo?ring)).tw,kf.		
9 or lab	((second or 2nd) adj1 (phase* or stage*) adj3 (birth* or childbirth* or deliver* po?r? or labo?red or labo?ring)).tw,kf.		
10 (birth	((phase two or phase 2 or stage two or stage 2 or phase II or stage II) adj3 * or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf.		
11	(intrapartu* or partu* or perinat* or peri nat* or peripartu*).tw,kf.		
12	or/1-11		
13	water/		
14	water birth/		
15	water immersion labor pool/		
16	water immersion/		
17	immersion/		
18	birthing pool/		
19	hydrotherapy/		
20 labo?	((immers* or water* or underwater*) adj3 (birth* or childbirth* or deliver* or rabo?red or labo?ring)).tw,kf.		
21 labo?	((bath* or pool? or tub?) adj3 (birth* or childbirth* or deliver* or labo?r? or red or labo?ring)).tw,kf.		
22	(hydrotherap* or hydro therap*).tw,kf.		
23	or/13-22		
24	12 and 23		
25	limit 24 to english language		
26	animal/		
27	nonhuman/		
28	exp Animal Experiment/		
29	exp Experimental Animal/		
30	animal model/		
31	exp Rodent/		

Searches 32 (rat or rats or mouse or mice or rodent*).ti. 33 or/26-32 34 33 not human/ 25 not 34 35 36 letter.pt. or letter/ 37 note.pt. 38 editorial.pt. 39 (letter or comment*).ti. or/36-39 40 41 randomized controlled trial/ or random*.ti,ab. 42 40 not 41 35 not 42 43 44 43 not clinical trial.pt. 44 not conference*.db,pt,su. 45 46 Health economics/ 47 exp health care cost/ 48 exp Fee/ 49 exp Budget/ 50 Funding/ 51 budget*.ti,ab. 52 cost*.ti. 53 (economic* or pharmaco?economic*).ti. 54 (price* or pricing*).ti,ab. 55 (cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab. (financ* or fee or fees).ti,ab. 56 57 (value adj2 (money or monetary)).ti,ab. or/46-57 58 59 45 and 58 60 limit 59 to dc=20050101-20250521 61 limit 59 to dd=20050101-20250521 62 60 or 61

1 Database name: International HTA Database (INAHTA)

Searches 16 limit 15 to year 2005-2025 15 limit 14 to English language 14 #13 AND #8 13 #12 OR #11 OR #10 OR #9

- 12 (waterbirth* OR ((immers* or water* or underwater*) AND (birth* or childbirth* or deliver* or labor or labors or labour or labours or labored or laboured or laboring or labouring)) OR ((bath* or pool or pools or tub or tubs) AND (birth* or childbirth* or deliver* or labor or labors or labour or labours or labored or laboring or labouring)) OR (hydrotherap* or "hydro therapy" or "hydro therapies"))
 32
- 11 "Hydrotherapy"[mh]
- 10 "Immersion"[mh]
- 9 "Water"[mh]
- 8 #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1
- 7 (intrapartu* or partu* or perinat* or "peri natal" or "peri natally" or peripartu*)
- 6 ((during or give or giving or push* or "phase two" or "phase 2" or "stage two" or "stage 2" or "phase ii" or "stage ii" or ((second or 2nd) AND (phase* or stage*))) AND (birth* or childbirth* or deliver* or labor or labors or labour or laboured or laboring or labouring))
- 5 "Perinatal Care"[mh]
- 4 "Parturition"[mhe]
- 3 "Delivery, Obstetric"[mhe]
- 2 "Labor, Obstetric"[mh]
- 1 "Labor Stage, Second"[mh]

1 Database name: MEDLINE

Searches

- # Searches
- 1 Labor Stage, Second/
- 2 Labor, Obstetric/
- 3 exp Delivery, Obstetric/
- 4 exp Parturition/
- 5 Perinatal Care/
- 6 ((during or give or giving or push*) adj5 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf.
- 7 ((second or 2nd) adj1 (phase* or stage*) adj3 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf.
- 8 ((phase two or phase 2 or stage two or stage 2 or phase II or stage II) adj3 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf.
- 9 (intrapartu* or partu* or perinat* or peri nat* or peripartu*).tw,kf.
- 10 or/1-9
- 11 Water/
- 12 Immersion/
- 13 Hydrotherapy/
- 14 waterbirth*.tw,kf.

- 15 ((immers* or water* or underwater*) adj3 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf.
- 16 ((bath* or pool? or tub?) adj3 (birth* or childbirth* or deliver* or labo?r? or labo?red or labo?ring)).tw,kf.
- 17 (hydrotherap* or hydro therap*).tw,kf.
- 18 or/11-17
- 19 10 and 18
- 20 limit 19 to english language
- 21 animals/
- 22 exp Animals, Laboratory/
- 23 exp Animal Experimentation/
- 24 exp Models, Animal/
- 25 exp Rodentia/
- 26 (rat or rats or mouse or mice or rodent*).ti.
- 27 or/21-26
- 28 27 not humans/
- 29 20 not 28
- 30 letter/
- 31 editorial/
- 32 news/
- 33 exp historical article/
- 34 Anecdotes as Topic/
- 35 comment/
- 36 (letter or comment*).ti.
- 37 or/30-36
- 38 randomized controlled trial/ or random*.ti,ab.
- 39 37 not 38
- 40 29 not 39
- 41 40 not overall.pt.
- 42 Economics/
- 43 Value of life/
- 44 exp "Costs and Cost Analysis"/
- 45 exp Economics, Hospital/
- 46 exp Economics, Medical/
- 47 Economics, Nursing/
- 48 Economics, Pharmaceutical/
- 49 exp "Fees and Charges"/
- 50 exp Budgets/
- 51 budget*.ti,ab.
- 52 cost*.ti.
- 53 (economic* or pharmaco?economic*).ti.

Searches 54 (price* or pricing*).ti,ab. 55 (cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab. 56 (financ* or fee or fees).ti,ab. 57 (value adj2 (money or monetary)).ti,ab. 58 or/42-57 59 41 and 58 60 limit 59 to ed=20050101-20250521 61 limit 59 to dt=20050101-20250521 60 or 61 62

1

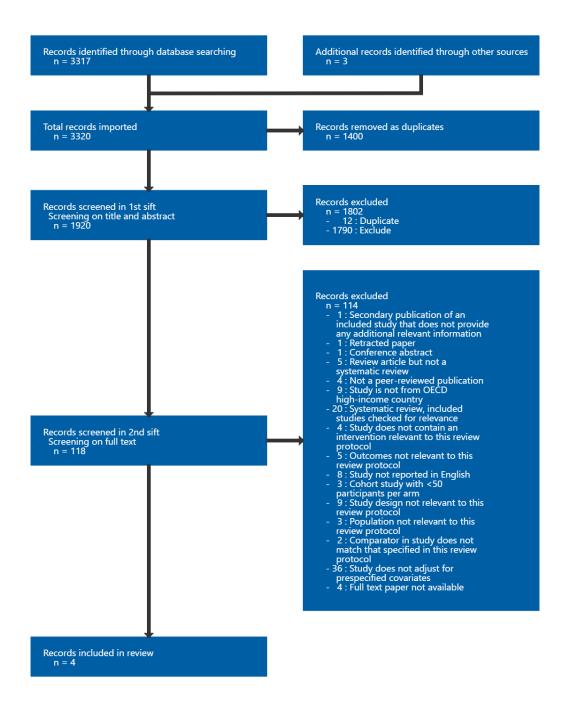
1 Appendix C - Study selection - effectiveness evidence

2 Figure 1: Effectiveness evidence study selection

3

4

5



Appendix D - Effectiveness evidence tables

23 Aughey, 2021

Bibliographic Reference

Aughey, H; Jardine, J; Moitt, N; Fearon, K; Hawdon, J; Pasupathy, D; Urganci, I; Harris, T; Waterbirth: a national retrospective cohort study of factors associated with its use among women in England.; BMC pregnancy and childbirth; 2021; vol. 21 (no. 1); 256

45 Study details

Country/ies where study was carried out	UK
Study type	Retrospective cohort study
Study dates	April 2015 - March 2016
Inclusion criteria	Women aged 18-44 years with BMI <35 kg/m² and without pre-existing medical conditions or previous obstetric complication or conditions arising in pregnancy who gave birth at term (37 ⁺⁰ to 42 ⁺⁶ weeks of gestation) and had a spontaneous vaginal delivery Note: The study stated that low and intermediate-risk (not defined) singleton term spontaneous vaginal births were included, and the number of participants with intermediate risk was not reported. However, it also stated that women had no risk factors requiring them to give birth in an obstetric unit according to national guidelines, therefore, we assumed that the majority of participants had low risk pregnancies.
Exclusion criteria	Breech presentation, instrumental birth, caesarean birth, and high-risk pregnancy
Patient characteristics	Maternal age (N for different age groups)*: 18-24 years: 9569 25-29 years: 13810 30-34 year: 14359 35-39 years: 7142

```
40-44 years: 1208
Gestation age in weeks (range)*: 37<sup>+0</sup> - 42<sup>+6</sup>
Parity (N)*:
Parity 0: 17206
Parity 1: 18914
Parity 2: 6691
Parity 3+: 3277
Ethnicity (N)*:
White: 37581
Black: 2339
Asian: 4506
Other: 143
BMI in kg/m<sup>2</sup> (N reported for different BMI groups)*:
18.5-24.9 kg/m<sup>2</sup>: 27011
25.0-29.9 kg/m<sup>2</sup>: 13698
30-34.9 kg/m<sup>2</sup>: 5379
Birthweight in g (N)*:
<2500 g: 594
2500-4000 g: 40204
≥4000 g: 5290
Socioeconomic status (N reported for each quintile; quintile 1 is the least deprived and quintile 5 is the most
deprived)*:
Quintile 1: 9450
Quintile 2: 7278
Quintile 3: 10120
Quintile 4: 10049
```

	Quintile 5: 9191
	Birth setting*: home and midwifery-led unit
	Water temperature: NR
	Duration of immersion in water in hours or minutes: NR
	Type of bath/tub/pool*: pool (the study stated pool but the type of pool was unclear)
	Active management of the third stage of labour: NR
	Perineal compression: NR
	*Data not reported separately for each group, and the study stated that data were obtained from Maternity Information System and Hospital Episodes Statistics (i.e., hospital setting). It was unclear whether the data from midwifery-led units located within community were used.
Intervention(s)/control	Water birth: having water birth or giving birth in water Birth out of water: not having water birth
Duration of follow-up	NR
Sources of funding	Not industry funded - The study was funded by NHS England and the Scottish and Welsh Governments
Sample size	N=46088 Water birth: N=6264 Birth out of water: N=39824
Other information	The study stated that no information was available about the women who labour in water but do not deliver in water, therefore it is possible that a proportion of women from water birth group may have spent time in a pool during labour, but not actually given birth in water.
	Multivariate logistic regression was used to control for maternal age, maternal BMI, parity, ethnicity, socio-economic status, and birthweight.

6

It was unclear how postpartum haemorrhage was measured in water.

Abbreviations: BMI: body mass index; NR: not reported

Water birth versus Birth out of water

Outcome	Water birth, N = 6264	Birth out of water, N = 39824
Perineal trauma (OASI or third/fourth-degree tear) (at birth) Water birth: 221/6264; Birth out of water: 1259/39824	1.00 (0.86, 1.16)	
Adjusted OR (95% CI)*		
Postpartum haemorrhage (≥1500 ml) (Follow-up period: NR) Water birth: 56/6264; Birth out of water: 496/39824	0.68 (0.51, 0.90)	
Adjusted OR (95% CI)*		
Neonatal unit admission (Follow-up period: NR) Water birth: 119/6264; Birth out of water: 1168/39824	0.65 (0	0.53, 0.78)
Adjusted OR (95% CI)*		

Abbreviations: CI: confidence interval; NR: not reported; OASI: obstetric anal sphincter injury * Adjusted for age, maternal BMI, parity, ethnicity, socio-economic status, and birthweight

Critical Appraisal - ROBINS-I: a tool for non-randomised studies of interventions

Section	Question	Answer
1. Bias due to confounding	Risk of bias judgement for confounding	Low (The study controlled for prespecified covariates (age, ethnicity, parity, birthweight, and socio-economic status).)

1
2
3

Bailey, 2020

Overall bias

Section

interventions

from intended interventions

data

outcomes

reported result Overall bias

2. Bias in selection of

participants into the study

3. Bias in classification of

4. Bias due to deviations

5. Bias due to missing

7. Bias in selection of the

Question

the study

interventions

missing data

Directness

6. Bias in measurement of Risk of bias judgement for

measurement of outcomes

Risk of bias judgement for

Risk of bias judgement

deviations from intended

classification of interventions

selection of participants into

Bibliographic
Reference

Bailey, Joanne M; Zielinski, Ruth E; Emeis, Cathy L; Kane Low, Lisa; A retrospective comparison of waterbirth outcomes in two United States hospital settings.; Birth (Berkeley, Calif.); 2020; vol. 47 (no. 1); 98-104

selection of the reported result (No indication of selection of the reported analysis from among multiple analyses.)

in water and water temperature provided.)

(No deviations from intended interventions)

(Outcome data was available for all or nearly all participants.)

(The outcome measure was unlikely to be influenced by knowledge of the

admission, and postpartum haemorrhage are objective outcomes.)

intervention received by study participants, and perineal trauma, neonatal unit

(All participants who would have been eligible for the trial were included in the

(No clear information on type of pool, and no information on duration of immersion

Study details

Answer

Low

Low

Low

Low

Moderate

Moderate

Directly applicable

study.)

Moderate

Country/ies where study was carried out	USA
Study type	Retrospective cohort study
Study dates	2006 - 2015
Inclusion criteria	Women with singleton low-risk term pregnancy (gestation age >37 weeks) in cephalic presentation, reassuring maternal and fetal condition during labour, who agreed to exit tub if advised to do so
Exclusion criteria	Fetal compromise identified by fetal heart tracing, meconium-stained fluid, excessive bleeding, presence of infection (e.g., HIV, hepatitis B, herpes simplex virus infection), type 1 diabetes, suspected macrosomia, chorioamnionitis, abnormal cardiac function, history of shoulder dystocia, BMI >40 kg/m², current use of narcotics or epidural, preeclampsia, use of fetal scalp electrode, and inability to monitor fetal heart rate as appropriate for the risk category of patients
Patient characteristics	Maternal age in years, mean (range): Water birth: 30.8 (17-45) Land birth: 31.0 (17-46) Gestation age in weeks*: >37 Parity: Water birth: Nulliparous N=129; Multiparous N=248 Land birth: Nulliparous N=131; Multiparous N=266 Ethnicity: Water birth: White N=313; Black N=14; Other N=42 Land birth: White N=329; Black=16; Other N=52 BMI in kg/m²; mean (range): Water birth: 24.0 (15.8-41.1) Land birth: 24.0 (16-39.4) Birthweight in g; mean (SD): NR

Socioeconomic factor (Insurance) (N): Water birth: Private N=270; Medicaid (Public) N=75 Land birth: Private N=312; Medicaid (Public) N=85 Birth setting within tertiary care hospitals: midwifery-led units Water temperature: NR Duration of immersion in water in hours or minutes: NR Type of bath/tub/pool: tub (no details/clear information on the type of tub provided) Active management of third stage of labour with intramuscular oxytocin (N): Water birth: Yes N=176: No N=216 Land birth: Yes N=217; No N=166 Perineal compression: NR *Data not reported separately for each group Intervention(s)/control Water birth: water immersion (hydrotherapy) in labour and birth Land birth: water immersion (hydrotherapy) only in labour or no water immersion **Duration of follow-up** NR Sources of funding NR Sample size N=794** (Whole cohort N=2422) Water birth: N=397 Land birth: N=397 **Matched cohort was N=794 (maternal age, race/ethnicity, parity, insurance, BMI, and site were matched), and the data on matched cohort was reported in this review.

Other information 47.3% of participants from land birth group had hydrotherapy in labour, and 100% of participants from water birth group had hydrotherapy in labour and birth The study matched for maternal age, race/ethnicity, parity, insurance, site, BMI, and history of prior caesarean section, but birthweight and other important socio-economic factors were not adjusted for.

It was unclear how postpartum haemorrhage was measured in water. Abbreviations: HIV: human immunodeficiency virus; NR: not reported; SD: standard deviation

Water birth versus Land birth

Water birth, N = 397	Land birth, N = 397
11/397	14/397
0/397	0/397
38/391	47/383
5/391	8/383
7/396	8/394
	11/397 0/397 38/391 5/391

Abbreviations: NR: not reported

Critical Appraisal - ROBINS-I: a tool for non-randomised studies of interventions

Section	Question	Answer
Bias due to confounding	Risk of bias judgement for confounding	Moderate (The study controlled for maternal age, race/ethnicity, parity, and insurance, but birthweight and other important socio-economic factors were not adjusted for.)
2. Bias in selection of participants into the study	Risk of bias judgement for selection of participants into the study	Low (All eligible participants were included and followed up in the trial.)
3. Bias in classification of interventions	Risk of bias judgement for classification of interventions	Moderate (No clear information on type of tub, and no information on duration of immersion in water and water temperature provided.)
4. Bias due to deviations from intended interventions	Risk of bias judgement for deviations from intended interventions	Low (No deviations from intended interventions.)
5. Bias due to missing data	Risk of bias judgement for missing data	Low (Outcome data was available for all or nearly all participants.)
6. Bias in measurement of outcomes	Risk of bias judgement for measurement of outcomes	Low (The outcome measure was unlikely to be influenced by knowledge of the intervention received by study participants, and mortality, perineal trauma, neonatal unit admission and postpartum haemorrhage are objective outcomes.)
7. Bias in selection of the reported result	Risk of bias judgement for selection of the reported result	Moderate (There is no indication of selection of the cohort or subgroups for analysis and reporting on the basis of the results, but perinatal mortality that was not prespecified in the method section was reported. Therefore, it cannot be considered comparable to a well-performed randomised trial.)
Overall bias	Risk of bias judgement	Moderate
Overall bias	Directness	Directly applicable

Bovbjerg, M L; Cheyney, M; Caughey, A B; Maternal and neonatal outcomes following waterbirth: a cohort study of 17 530

waterbirths and 17 530 propensity score-matched land births.; BJOG: an international journal of obstetrics and

gynaecology; 2022; vol. 129 (no. 6); 950-958

2 3

Study details

Country/ies where study was carried out	USA
Study type	Retrospective cohort study
Study dates	2012-2018
Inclusion criteria	Women who gave birth at home or in a birth centre (low-risk births in community), whose fetus was born alive and did not have a congenital anomaly, and did not have high risk pregnancy or missing data for water birth
Exclusion criteria	Intrapartum transfer to hospital
Patient characteristics	Maternal age in years; mean (95% CI): Water birth: 30.7 (30.6-30.7) Land birth: 30.7 (30.6-30.7) Gestation age in days; mean (95% CI): Water birth: 281.1 (281.0-281.1) Land birth: 281.0 (280.9-281.0) Parity; % (95% CI)*: Primiparous: Water birth: 26.5 (26.2-26.7) Land birth: 26.4 (26.1-26.6) Ethnicity; % (95% CI)**: White:

```
Water birth: 86.5 (86.2-86.7)
Land birth: 86.5 (86.3-86.7)
BMI in kg/m<sup>2</sup>; (% (95% CI) reported for different BMI groups):
Water birth:
<25 kg/m<sup>2</sup>: 64.6 (64.2-64.9)
25-30 kg/m<sup>2</sup>: 19.0 (18.7-19.3)
30-<35 kg/m<sup>2</sup>: 6.9 (6.6-7.0)
35+ kg/m<sup>2</sup>: 3.4 (3.3-3.6)
Missing: 6.2 (6.0-6.3)
Land birth:
<25 kg/m<sup>2</sup>: 64.7 (64.4-64.9)
25-30 kg/m<sup>2</sup>: 19.0 (18.8-19.2)
30-<35 kg/m<sup>2</sup>: 6.8 (6.7-7.0)
35+ kg/m<sup>2</sup>: 3.4 (3.3-3.5)
Missing: 6.1 (6.0-6.3)
Birthweight in grams: NR
Socioeconomic factor; % (95% CI):
Water birth:
Maternal education (e.g., a bachelor's degree or more): 49.3 (48.9-49.7)
Mother eligible for Medicaid: 23.4% (23.0-23.7)
Land birth:
Maternal education (e.g., a bachelor's degree or more): 49.5 (49.2-49.7)
Mother eligible for Medicaid: 23.8 (23.5-24.0)
Birth setting within community; % (95% CI):
Water birth:
Home: 73.7 (73.3-74.0)
```

	Birth centre: 26.2 (25.9-26.6)
	Land birth: Home: 73.3 (73.0-73.5) Birth centre: 26.6 (26.4-26.8)
	Water temperature: NR
	Duration of immersion in water in hours or minutes: NR
	Type of bath/tub/pool: NR
	Active management of the third stage of labour (N): NR***
	Perineal compression: NR
	*Data only reported for primiparous ** Data only reported for white ethnicity ***It was not reported but the study was conducted in the community and stated that midwives practicing in community settings are trained to facilitate and support physiologic birth, without interventions common in hospitals (eg., caesarean, synthetic oxytocin, and epidural). Therefore, it is very likely that participants did not receive active management of 3 rd stage of labour.
Intervention(s)/control	Water birth: under water birth Land birth: unexposed to water birth
Duration of follow-up	6 weeks after birth
Sources of funding	Not industry funded - The study was funded by the United States Department of Health & Human Services, NICHD/NIH R03HD096094, the J. William Fulbright Scholarship Board and the Fulbright Commission in Ireland
Sample size	N=35060**** (Whole cohort N=62361) Water birth: N=17530 Land birth: N=17530

	****Matched cohort was reported in the review, and propensity score-matched on over 80 demographic and pregnancy risk covariables, including maternal age, parity, ethnicity, and socio-economic factors.
Other information	In addition to matching, the study used logistic regression to control for over 80 demographic and pregnancy risk covariables. It was unclear how postpartum haemorrhage was measured in water.

Abbreviations: BMI: body mass index; CI: confidence interval; NR: not reported

Water birth versus Land birth

Outcome	Water birth, N = 17530	Land birth, N = 17530
Perineal trauma (third/fourth-degree tear) (at birth) Water birth: 131/17530; Land birth: 147/17530	0.90 (0.8	31, 0.99)
Adjusted OR (95% CI)*		
Neonatal mortality (through 27 complete days) Water birth: 5/17530; Land birth: 9/17530	0.56 (0.3	31, 1.00)
Adjusted OR (95% CI)*		
Postpartum haemorrhage (defined as "Diagnosed with haemorrhage in 3rd or 4th stage of labour") Water birth: 822/17530; Land birth: 952/17530	0.86 (0.8	32, 0.90)
Adjusted OR (95% CI)*		
Neonatal unit admission (in the first 6 weeks) Water birth: 323/17530; Land birth: 340/17530	0.95 (0.8	39, 1.02)
Adjusted OR (95% CI)*		

onatal unit admission - Neonatal infection (in the first 6 weeks) ater birth: 158/17530; Land birth: 160/17530	0.99 (0.9	90, 1.09)
justed OR (95% CI)*		
onatal unit admission - Respiratory distress syndrome (Follow up period: NR) ater birth: 261/17530; Land birth: 282/17530	0.93 (0.8	86, 0.99)
justed OR (95% CI)*		
apped umbilical cord (umbilical cord avulsion) (at birth) ater birth: 100/17530; Land birth: 65/17530	1.57 (1.3	37, 1.82)
justed OR (95% CI)*		

Abbreviations: NR: not reported

Critical Appraisal - ROBINS-I: a tool for non-randomised studies of interventions

Section	Question	Answer
1. Bias due to confounding	Risk of bias judgement for confounding	Moderate (The study controlled for maternal age, race/ethnicity, parity, and socioeconomic factors (such as maternal education and insurance), but birthweight and other important socioeconomic factors were not adjusted for.)
2. Bias in selection of participants into the study	Risk of bias judgement for selection of participants into the study	Low (All eligible participants were included and followed up in the trial.)
3. Bias in classification of interventions	Risk of bias judgement for classification of interventions	Moderate (No information on type of tub/pool, duration of immersion in water and water temperature provided)

^{*} Adjusted for over 80 demographic and pregnancy risk covariables, including maternal age, parity, ethnicity, and socio-economic factors

Section	Question	Answer
4. Bias due to deviations from intended interventions	Risk of bias judgement for deviations from intended interventions	Low (No deviations from intended interventions.)
5. Bias due to missing data	Risk of bias judgement for missing data	Low (Outcome data was available for all or nearly all participants.)
6. Bias in measurement of outcomes	Risk of bias judgement for measurement of outcomes	Low (The outcome measure was unlikely to be influenced by knowledge of the intervention received by study participants, and mortality, perineal trauma, neonatal unit admission, postpartum haemorrhage, and snapped umbilical cord are objective outcomes.)
7. Bias in selection of the reported result	Risk of bias judgement for selection of the reported result	Moderate (There is no indication of selection of the cohort or subgroups for analysis and reporting on the basis of the results for all outcomes, except for postpartum haemorrhage (e.g., haemorrhage in 3 rd and 4 th stage of labour was reported, but postpartum transport to a hospital because of haemorrhage or maternal hospitalisation in the first 6 weeks because of haemorrhage were not reported. Therefore, it cannot be considered comparable to a well-performed randomised trial.)
Overall bias	Risk of bias judgement	Moderate
Overall bias	Directness	Directly applicable (Perineal trauma, neonatal mortality, neonatal unit admission, and umbilical cord avulsion are directly applicable, but postpartum haemorrhage is indirectly applicable because it was defined as haemorrhage in 3rd or 4th stage of labour, regardless of estimated blood loss.)

Sanders, 2024

Bibliographic Reference

Sanders, Julia; Barlow, Christy; Brocklehurst, Peter; Cannings-John, Rebecca; Channon, Susan; Cutter, Judith; Hunter, Billie; Jokinen, Mervi; Lugg-Widger, Fiona; Milosevic, Sarah; Gale, Chris; Milton, Rebecca; Morantz, Leah; Paranjothy, Shantini; Plachcinski, Rachel; Robling, Michael; Maternal and neonatal outcomes among spontaneous vaginal births

occurring in or out of water following intrapartum water immersion: The POOL cohort study.; BJOG: an international journal of obstetrics and gynaecology; 2024; vol. 131 (no. 12); 1650-1659

Study details

Country/ies where study was carried out	UK
Study type	Prospective cohort study Retrospective cohort study
Study dates	January 2015 - June 2022
Inclusion criteria	Women without antenatal or intrapartum risk factors that indicate that birth in an obstetric unit should be recommended who are in spontaneous labour between 37 ⁺⁰ and 41 ⁺⁶ weeks of gestation (low-risk pregnancy)
Exclusion criteria	Women who need continuous electronic fetal heart rate monitoring or epidural analgesia, obstetric or anaesthetic interventions before birth (such as operative or instrumental birth), and augmentation of labour with Syntocinon, and gave birth without the attendance of a midwife (e.g., women wanted to give birth without assistance of a professional or birth occurred at home or elsewhere prior to the arrival of professional assistance)
Patient characteristics	Maternal age in years; mean (SD): Water birth: 29.9 (5.0) Birth out of water: 28.8 (5.2) Gestation age at birth in weeks; mean (SD)*: Water birth: 40.1 (1.0) Birth out of water: 40.2 (1.0) Parity: Water birth: Nulliparous N=15176; Multiparous N=24451 Birth out of water: Nulliparous N=12210; Multiparous N=8565 Ethnicity:

Water birth: White N=32420; Asian or Asian British N=1643; Black or Black British or Caribbean or African N=686; Mixed or multiple ethnic groups N=595; Other ethnic group N=1096; Declined to answer/Not recorded N=3187 Birth out of water: White N=16395; Asian or Asian British N=1006; Black or Black British or Caribbean or African N=351; Mixed or multiple ethnic groups N=280; Other ethnic group N=611; Declined to answer/Not recorded N=2132

BMI in kg/m²; mean (SD): Water birth: 24.3 (3.7) Birth out of water: 24.0 (3.8)

Birthweight in g; mean (SD): Water birth: 3518 (409) Birth out of water: 3511 (421)

Socioeconomic factor or Deprivation quintile by Townsend (quintile 1 is the most affluent and quintile 5 is the most deprived):

Water birth**: Quintile 1 N=8605; Quintile 2 N=9435; Quintile 3 N=8488; Quintile 4 N=6905; Quintile 5 N=5475 Birth out of water***: Quintile 1 N=3887; Quintile 2 N=4579; Quintile 3 N=4435; Quintile 4 N=3913; Quintile 5 N=3472

Birth setting within hospital and community****: home, midwifery-led unit, and obstetric unit

Water temperature: NR

Duration of immersion in water in hours or minutes: NR

Type of bath/tub/pool: domestic bath or specialist birthing pool

Active management of the third stage of labour (N): NR

Perineal compression: NR

*Data were not available for N=195
**Data were not available for N=719

	Data were not available for N=489 *Data not reported separately for each setting
Intervention(s)/control	Water birth: water immersion during labour and birth (giving birth in water) Birth out of water: leaving the water before birth
Duration of follow-up	Duration of follow-up was reported for the following outcomes: fetal mortality (stillbirth) after the start of care in labour, neonatal mortality before discharge home, and neonatal unit admission with administration of intravenous antibiotics started within 48 hours of birth Duration of follow-up was not reported for the remaining outcomes
Sources of funding	Not industry funded - The study was funded by the National Institute for Health and Care Research (NIHR)
Sample size	N=60402 Water birth: N=39627 Birth out of water: N=20775
Other information	Births in which the fetus was partially born into water remained in the water birth group even if the birth was completed out of water (including previously unrecognised breech presentation or shoulder dystocia). The study did not report data on hypoxic-ischaemic encephalopathy, but it stated that babies with a snapped cord did not receive therapeutic hypothermia for treatment of neonatal encephalopathy or a blood transfusion. It was unclear how postpartum haemorrhage was measured in water.
Abbraviationa, BML bady mag	s index: NP: not reported: SD: standard deviation

Abbreviations: BMI: body mass index; NR: not reported; SD: standard deviation

Water birth versus Birth out of water

Outcome	Water birth, N = 39627	Birth out of water, N = 20775
Perineal trauma (OASI or third/fourth-degree tear) (Nulliparous and multiparous women) (at birth) Water birth: 999/39627; Birth out of water: 785/20775	$0.89 \ (-\infty \ \text{to} \ 0.98)^2$	
Adjusted OR ¹ (1-sided 95% CI)		

Outcome	Water birth, N = 39627	Birth out of water, N = 20775
Perineal trauma (OASI or third/fourth-degree tear) (Nulliparous women) (at birth) Water birth: 730/15176; Birth out of water: 641/12210	0.97 (0	.86 to 1.11)
Adjusted OR ¹ (95% CI)		
Perineal trauma (OASI or third/fourth-degree tear) (Multiparous women) (at birth) Water birth: 269/24451; Birth out of water: 144/8565	0.64 (0	.51 to 0.80)
Adjusted OR ¹ (95% CI)		
Fetal and neonatal mortality (Nulliparous and multiparous women) (in labour or before discharge home) Water birth: 7/39627; Birth out of water: 6/20775	0.22 (-	∞ to 0.80) ³
Adjusted OR ¹ (1-sided 95% CI)		
Postpartum haemorrhage (≥500 ml) (Nulliparous and multiparous women) (Follow-up period: NR)	5199/39627	3329/20775
No of events		
Postpartum haemorrhage (≥1000 ml) (Nulliparous and multiparous women) (Follow-up period: NR) Water birth: 1165/39627; Birth out of water: 797/20775	0.90 (-	·∞ to 0.98)⁴
Adjusted OR ¹ (1-sided 95% CI)		
Postpartum haemorrhage (≥1500 ml) (Nulliparous and multiparous women) (Follow-up period: NR)	445/39627	274/20775
No of events		

Outcome	Water birth, N = 39627	Birth out of water N = 20775
Neonatal unit admission (Nulliparous and multiparous women) (Follow-up period: NR) Water birth: 1455/39627; Birth out of water: 1203/20775	0.66 (-	∞ to 0.71) ⁵
Adjusted OR¹ (1-sided 95% CI)		
Neonatal unit admission - Respiratory support (Nulliparous and multiparous women) (Follow-up period: NR) Water birth: 329/39627; Birth out of water: 320/20775	0.58 (-	∞ to 0.68) ⁶
Adjusted OR¹ (1-sided 95% CI)		
Neonatal unit admission - Administration of intravenous antibiotics commenced within 48 h of birth (Nulliparous and multiparous women) (Prospective study population) Water birth: 181/9868; Birth out of water: 149/5078 Adjusted OR ¹ (1-sided 95% CI)	0.74 (-	∞ to 0.94) ⁷
Neonatal unit admission - Administration of intravenous antibiotics commenced within 48 h of birth (Nulliparous and multiparous women) (National Neonatal Research Database) Water birth: 629/35090; Birth out of water: 535/18693	0.69 (-	∞ to 0.77) ⁸
Adjusted OR¹ (1-sided 95% CI)		
Snapped umbilical cord (before clamping) (Nulliparous and multiparous women) (at birth) Water birth: 106/10760; Birth out of water: 16/5463	3.89 (-	∞ to 6.88) ⁹
Adjusted OR ¹ (1-sided 95% CI)		
Abbroviations: Cl. confidence interval: NP: not reported: OASI: electotric anal enhineter injuny		

Abbreviations: CI: confidence interval; NR: not reported; OASI: obstetric anal sphincter injury

Adjusted for year and quarter of birth, ethnicity, socio-economic status or deprivation quintile, maternal age, gestational age, parity, maternal body mass index, birthweight, and concern identified by midwife before birth

Two-sided 95% CI calculated by NICE: 0.79 to 0.99

Two-sided 95% CI calculated by NICE: 0.05 to 1.02

Two-sided 95% CI calculated by NICE: 0.81 to 0.99

Critical Appraisal - ROBINS-I: a tool for non-randomised studies of interventions

Section	Question	Answer
Bias due to confounding	Risk of bias judgement for confounding	Low (All prespecified covariates (age, ethnicity, parity, birthweight, and socio-economic status) were adjusted for.)
2. Bias in selection of participants into the study	Risk of bias judgement for selection of participants into the study	Low (All eligible participants were included and followed up in the trial.)
3. Bias in classification of interventions	Risk of bias judgement for classification of interventions	Moderate (No information on duration of immersion in water and water temperature provided.)
4. Bias due to deviations from intended interventions	Risk of bias judgement for deviations from intended interventions	Low (No deviations from intended interventions)
5. Bias due to missing data	Risk of bias judgement for missing data	Low (Outcome data was available for all or nearly all participants)
6. Bias in measurement of outcomes	Risk of bias judgement for measurement of outcomes	
7. Bias in selection of the reported result	Risk of bias judgement for selection of the reported result	Moderate (No indication of selection of the reported analysis from among multiple analyses, but postpartum haemorrhage ≥500 ml and postpartum haemorrhage ≥1500 ml that were not

Two-sided 95% CI calculated by NICE: 0.60 to 0.72
 Two-sided 95% CI calculated by NICE: 0.48 to 0.70
 Two-sided 95% CI calculated by NICE: 0.56 to 0.98
 Two-sided 95% CI calculated by NICE: 0.61 to 0.79
 Two-sided 95% CI calculated by NICE: 1.97 to 7.67

Section	Question	Answer
		prespecified in protocol were reported. Therefore, it cannot be considered comparable to a well-performed randomised trial.)
Overall bias	Risk of bias judgement	Moderate
Overall bias	Directness	Directly applicable

Appendix E - Forest plots

- 2 This section includes forest plots only for outcomes that are meta-analysed. Outcomes from single studies are not presented here;
- 3 the quality assessment for such outcomes is provided in the GRADE (Grading of Recommendations, Assessment, Development,
- 4 and Evaluations) summary tables in appendix F.
- 5 Water birth versus Birth out of water
- 6 Figure 2: Perineal trauma (third-degree or fourth-degree tear at birth) (Nulliparous and multiparous women) (Setting: home
- 7 and MWLD, and home and BC within community)

Study or Subgroup	log[OR]	SE	Weight	Odds ratio IV, Fixed, 95%	Odds ratio CI IV, Fixed, 95% CI
Aughey 2021	0	0.076339	31.0%	1.00 [0.86 , 1.7	16]
Bovbjerg 2022	-0.105361	0.051192	69.0%	0.90 [0.81 , 0.9	99]
Total			100.0%	0.93 [0.86 , 1.0	01]
Test for overall effect:	Z = 1.71 (P =	= 0.09)			0.2 0.5 1 2 5
Test for subgroup diffe	erences: Not	applicable			Favours water birth Favours birth out of water
Heterogeneity: Chi2 =	1.31, df = 1 ((P = 0.25):	l ² = 24%		

9 Abbreviations: BC: birth centre; CI: confidence interval; IV: inverse variance method; MWLD: midwifery-led unit; OR: odds ratio; SE: standard error

8

Appendix F - GRADE summary

Table 1 Effectiveness evidence summary: Water birth vs Birth out of water (Nulliparous women)

Outcomes		Certainty of the		Anticipated absolute effects ^e	
	№ of participants (studies) Follow-up	evidence (GRADE) and Clinical importance	Relative effect (95% CI)	Risk with Birth out of water	Risk difference with Water birth
Perineal trauma (third-degree or fourth-degree tear at birth) (Nulliparous) (Setting: home, MWLU, and OU within hospital and community)	27386 (1 non-randomised study) (Sanders 2024) ^a	Low ^{b,c} UN. EFFECT	Adjusted OR 0.97 (0.85 to 1.10) ^d	52 per 1,000	1 fewer per 1,000 (8 fewer to 5 more)

Abbreviations: CI: confidence interval; MWLD: midwifery-led unit; OR: odds ratio; OU: obstetric unit; UN. EFFECT: uncertain effect

Explanations

8

9

10

2

a. Sanders 2024: Water immersion during labour and birth (giving birth in water) vs. Leaving the water before birth

b. Serious risk of bias in the evidence contributing to the outcomes as per ROBINS-I

c. Downgraded once for inconsistency, as single study outcomes may otherwise receive favourable ratings for inconsistency by default

d. Adjusted for year and quarter of birth, ethnicity, socio-economic status or deprivation quintile, maternal age, gestational age, parity, maternal body mass index, birthweight, and concern identified by midwife before birth

e. The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI)

Table 2 Effectiveness evidence summary: Water birth vs Birth out of water (Multiparous women)

Outcomes		Certainty of the		Anticipated absolute effects ^e	
	№ of participants (studies) Follow-up	evidence (GRADE) and Clinical importance	Relative effect (95% CI)	Risk with Birth out of water	Risk difference with Water birth
Perineal trauma (third-degree or fourth-degree tear at birth) (Multiparous) (Setting: home, MWLU, and OU within hospital and community)	33016 (1 non-randomised study) (Sanders 2024) ^a	Low ^{b,c} EV. OF BENEFIT	Adjusted OR 0.64 (0.51 to 0.80) ^d	17 per 1,000	6 fewer per 1,000 (8 fewer to 3 fewer)

Abbreviations: CI: confidence interval; EV. OF BENEFIT: evidence of benefit; MWLD: midwifery-led unit; OR: odds ratio; OU: obstetric unit

34 Explanations

a. Sanders 2024: Water immersion during labour and birth (giving birth in water) vs. leaving the water before birth

6 b. Serious risk of bias in the evidence contributing to the outcomes as per ROBINS-I

7 c. Downgraded once for inconsistency, as single study outcomes may otherwise receive favourable ratings for inconsistency by default

8 d. Adjusted for year and quarter of birth, ethnicity, socio-economic status or deprivation quintile, maternal age, gestational age, parity, maternal body mass index, birthweight, and concern identified by midwife before birth

9 e. The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI)

Table 3 Effectiveness evidence summary: Water birth vs Birth out of water (Nulliparous and multiparous women)

		Certainty of the		Anticipated absolute effectse	
Outcomes	№ of participants (studies) Follow-up	evidence (GRADE) and Clinical importance	Relative effect (95% CI)	Risk with Birth out of water	Risk difference with Water birth
Perineal trauma (third-degree or fourth-degree tear at birth) (Nulliparous and multiparous) (Setting: MWLD within tertiary care hospitals)	794 (1 non-randomised study) (Bailey 2020)ª	Very low ^{b,c,d} UN. EFFECT	RR 0.79 (0.36 to 1.71)	35 per 1,000	7 fewer per 1,000 (23 fewer to 25 more)
Perineal trauma (third-degree or fourth-degree tear at birth) (Nulliparous and multiparous) (Setting: home, MWLU, and OU within hospital and community)	60402 (1 non-randomised study) (Sanders 2024) ^f	Low ^{b,c} EV. OF BENEFIT	Adjusted OR 0.89 (0.80 to 0.99) ^{g,h}	38 per 1,000	4 fewer per 1,000 (7 fewer to 0 fewer)
Perineal trauma (third-degree or fourth-degree tear at birth) (Nulliparous and multiparous) (Setting: home and MWLD, and home and BC within community)	81148 (2 non-randomised studies) (Aughey 2021; Bovbjerg 2022) ^{i,j}	Moderate ^b UN. EFFECT	Adjusted OR 0.93 (0.86 to 1.01) ^{k,l}	25 per 1,000	2 fewer per 1,000 (3 fewer to 0 fewer)

		Certainty of the		Anticipated absolute effectse	
Outcomes	№ of participants (studies) Follow-up	evidence (GRADE) and Clinical importance	Relative effect (95% CI)	Risk with Birth out of water	Risk difference with Water birth
Fetal and neonatal mortality (Perinatal death) (Nulliparous and multiparous) (Setting: MWLD within tertiary care hospitals)	794 (1 non-randomised study) (Bailey 2020)ª	Low ^{b,c} UN. EFFECT	Risk Difference 0.0000 (-0.0049 to 0.0049) ^m	0 per 1,000	0 fewer per 1,000 (5 fewer to 5 more) ⁿ
Fetal and neonatal mortality (in labour or before discharge home) (Nulliparous and multiparous) (Setting: home, MWLU, and OU within hospital and community)	60402 (1 non-randomised study) (Sanders 2024) ^f	Very low ^{b,c,d} UN. EFFECT	Adjusted OR 0.22 (0.05 to 1.02) ^{g,h}	0 per 1,000	0 fewer per 1,000 (0 fewer to 0 fewer)
Neonatal mortality (through 27 complete days) (Nulliparous and multiparous) (Setting: home and BC within community)	35060 (1 non-randomised study) (Bovbjerg 2022) ^j	Very low ^{b,c,d}	Adjusted OR 0.56 (0.31 to 1.01) ¹	1 per 1,000	0 fewer per 1,000 (0 fewer to 0 fewer)

Outcomes	X 2 6	Certainty of the		Anticipated absolute effectse	
	№ of participants (studies) Follow-up	evidence (GRADE) and Clinical importance	Relative effect (95% CI)	Risk with Birth out of water	Risk difference with Water birth
Postpartum haemorrhage (minor: 500-1000 ml) (Follow-up period: NR) (Nulliparous and multiparous) (Setting: MWLD within tertiary care hospitals)	774 (1 non-randomised study) (Bailey 2020)ª	Low ^{b,c} UN. EFFECT	RR 0.79 (0.53 to 1.19)	123 per 1,000	26 fewer per 1,000 (58 fewer to 23 more)
Postpartum haemorrhage (≥500 ml) (Follow-up period: NR) (Nulliparous and multiparous) (Setting: home, MWLU, and OU within hospital and community)	60402 (1 non-randomised study) (Sanders 2024) ^f	Low ^{b,c} EV. OF BENEFIT	RR 0.82 (0.79 to 0.85)	160 per 1,000	29 fewer per 1,000 (34 fewer to 24 fewer)
Postpartum haemorrhage (major: >1000 ml) (Follow-up period: NR) (Nulliparous and multiparous) (Setting: MWLD within tertiary care hospitals)	774 (1 non-randomised study) (Bailey 2020) ^a	Very low ^{b,c,d} UN. EFFECT	RR 0.61 (0.20 to 1.85)	21 per 1,000	8 fewer per 1,000 (17 fewer to 18 more)

		Certainty of the		Anticipated absolute effectse	
Outcomes	№ of participants (studies) Follow-up	evidence (GRADE) and Clinical importance	Relative effect (95% CI)	Risk with Birth out of water	Risk difference with Water birth
Postpartum haemorrhage (major: >1000 ml) (Follow-up period: NR) (Nulliparous and multiparous) (Setting: home, MWLU, and OU within hospital and community)	60402 (1 non-randomised study) (Sanders 2024) ^f	Low ^{b,c} EV. OF BENEFIT	Adjusted OR 0.90 (0.81 to 0.99) ^{g,h}	38 per 1,000	4 fewer per 1,000 (7 fewer to 0 fewer)
Postpartum haemorrhage (major: ≥1500 ml) (Follow-up period: NR) (Nulliparous and multiparous) (Setting: home, MWLU, and OU within hospital and community)	60402 (1 non-randomised study) (Sanders 2024) ^f	Low ^{b,c} EV. OF BENEFIT	RR 0.85 (0.73 to 0.99)	13 per 1,000	2 fewer per 1,000 (4 fewer to 0 fewer)
Postpartum haemorrhage (major: ≥1500 ml) (Follow-up period: NR) (Nulliparous and multiparous) (Setting: home and MWLU)	46088 (1 non-randomised study) (Aughey 2021) ⁱ	Low ^{b,c} EV. OF BENEFIT	Adjusted OR 0.68 (0.51 to 0.90) ^k	12 per 1,000	4 fewer per 1,000 (6 fewer to 1 fewer)

	N2 6 (1:1	Certainty of the		Anticipated absolute effectse	
Outcomes	№ of participants (studies) Follow-up	evidence (GRADE) and Clinical importance	Relative effect (95% CI)	Risk with Birth out of water	Risk difference with Water birth
Postpartum haemorrhage (defined as "Diagnosed with haemorrhage in 3rd or 4th stage of labour" by the study, regardless of estimated blood loss) (Nulliparous and multiparous) (Setting: home and BC within community)	35060 (1 non-randomised study) (Bovbjerg 2022) ^j	Very low ^{b,c,o} EV. OF BENEFIT	Adjusted OR 0.86 (0.82 to 0.90) ¹	54 per 1,000	7 fewer per 1,000 (9 fewer to 5 fewer)
Neonatal unit admission (Follow- up period: NR) (Nulliparous and multiparous) (Setting: MWLD within tertiary care hospitals)	790 (1 non-randomised study) (Bailey 2020)ª	Very low ^{b,c,d} UN. EFFECT	RR 0.87 (0.32 to 2.38)	20 per 1,000	3 fewer per 1,000 (14 fewer to 28 more)
Neonatal unit admission (Follow- up period: NR) (Nulliparous and multiparous) (Setting: home, MWLU, and OU within hospital and community)	60402 (1 non-randomised study) (Sanders 2024) ^f	Low ^{b,c} EV. OF BENEFIT	Adjusted OR 0.66 (0.60 to 0.72) ^{g,h}	58 per 1,000	19 fewer per 1,000 (22 fewer to 16 fewer)

		Certainty of the		Anticipated absolute effectse	
Outcomes	№ of participants (studies) Follow-up	evidence (GRADE) and Clinical importance	Relative effect (95% CI)	Risk with Birth out of water	Risk difference with Water birth
Neonatal unit admission (Follow- up period: NR) (Nulliparous and multiparous) (Setting: home and MWLU)	46088 (1 non-randomised study) (Aughey 2021) ⁱ	Low ^{b,c} EV. OF BENEFIT	Adjusted OR 0.65 (0.54 to 0.79) ^k	29 per 1,000	10 fewer per 1,000 (13 fewer to 6 fewer)
Neonatal unit admission (in the first 6 weeks) (Nulliparous and multiparous) (Setting: home and BC within community)	35060 (1 non-randomised study) (Bovbjerg 2022) ^j	Low ^{b,c} UN. EFFECT	Adjusted OR 0.95 (0.89 to 1.02) ¹	19 per 1,000	1 fewer per 1,000 (2 fewer to 0 fewer)
Neonatal unit admission - Neonatal infection (in the first 6 weeks) (Nulliparous and multiparous) (Setting: home and BC within community)	35060 (1 non-randomised study) (Bovbjerg 2022) ^j	Low ^{b,c} UN. EFFECT	Adjusted OR 0.99 (0.90 to 1.09) ¹	9 per 1,000	0 fewer per 1,000 (1 fewer to 1 more)

Outcomes		Certainty of the		Anticipated absolute effectse	
	№ of participants (studies) Follow-up	evidence (GRADE) and Clinical importance	Relative effect (95% CI)	Risk with Birth out of water	Risk difference with Water birth
Neonatal unit admission (Respiratory distress syndrome) (Follow-up period: NR) (Nulliparous and multiparous) (Setting: home and BC within community)	35060 (1 non-randomised study) (Bovbjerg 2022) ^j	Low ^{b,c} EV. OF BENEFIT	Adjusted OR 0.93 (0.87 to 0.99) ¹	16 per 1,000	1 fewer per 1,000 (2 fewer to 0 fewer)
Neonatal unit admission (Respiratory support) (Follow-up period: NR) (Nulliparous and multiparous) (Setting: home, MWLU, and OU within hospital and community)	60402 (1 non-randomised study) (Sanders 2024) ^f	Low ^{b,c} EV. OF BENEFIT	Adjusted OR 0.58 (0.48 to 0.70) ^{g,h}	15 per 1,000	6 fewer per 1,000 (8 fewer to 5 fewer)

	No. 6	Certainty of the	Relative effect (95% CI)	Anticipated absolute effectse	
Outcomes	№ of participants (studies) Follow-up	evidence (GRADE) and Clinical importance		Risk with Birth out of water	Risk difference with Water birth
Neonatal unit admission (Administration of intravenous antibiotics commenced within 48 h of birth; Prospective study population) (Nulliparous and multiparous) (Setting: home, MWLU, and OU within hospital and community)	14946 (1 non-randomised study) (Sanders 2024) ^f	Low ^{b,c} EV. OF BENEFIT	Adjusted OR 0.74 (0.56 to 0.98) ^{g,h}	29 per 1,000	7 fewer per 1,000 (13 fewer to 1 fewer)
Neonatal unit admission (Administration of intravenous antibiotics commenced within 48 h of birth; National Neonatal Research Database) (Nulliparous and multiparous) (Setting: home, MWLU, and OU within hospital and community)	53783 (1 non-randomised study) (Sanders 2024) ^f	Low ^{b,c} EV. OF BENEFIT	Adjusted OR 0.69 (0.61 to 0.79) ^{g,h}	29 per 1,000	9 fewer per 1,000 (11 fewer to 6 fewer)

No. of a constant		Certainty of the		Anticipated absolute effectse	
Outcomes	№ of participants (studies) Follow-up	evidence (GRADE) and Clinical importance	Relative effect (95% CI)	Risk with Birth out of water	Risk difference with Water birth
Snapped umbilical cord (cord avulsion at birth) (Nulliparous and multiparous) (Setting: home, MWLU, and OU within hospital and community)	16223 (1 non-randomised study) (Sanders 2024) ^f	Very low ^{b,c,d} EV. OF DISBENEFIT	Adjusted OR 3.89 (1.97 to 7.68) ^{g,h}	3 per 1,000	8 more per 1,000 (3 more to 19 more)
Snapped umbilical cord (cord avulsion at birth) (Nulliparous and multiparous) (Setting: home and BC within community)	35060 (1 non-randomised study) (Bovbjerg 2022) ^j	Low ^{b,c} EV. OF DISBENEFIT	Adjusted OR 1.57 (1.36 to 1.81) ^L	4 per 1,000	2 more per 1,000 (1 more to 3 more)

Abbreviations: BC: birth centre; CI: confidence interval; EV. OF BENEFIT: evidence of benefit; EV. OF DISBENEFIT: evidence of disbenefit; MWLD: midwifery-led unit; NR: not reported; OR: odds ratio; OU: obstetric unit; RR: risk ratio; UN. EFFECT: uncertain effect

Explanations

3

- a. Bailey 2020: Water immersion (hydrotherapy) in labour and birth vs. Water immersion (hydrotherapy) only in labour or no water immersion
- b. Serious risk of bias in the evidence contributing to the outcomes as per ROBINS-I
- c. Downgraded once for inconsistency, as single study outcomes may otherwise receive favourable ratings for inconsistency by default
- 8 d. The ratio of the upper to lower boundary of the confidence interval is more than 2.5 for odds ratio or 3 for risk ratios
- 9 e. The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

n water) vs. Leaving the water before	ing hirth in water) vs	labour and hirth (givi	Nater immersion during	f Sanders 2024: V	ı
n water) vs. Leaving the water befor	ing birth in water) vs.	labour and birth (givi	Nater immersion during	 Sanders 2024: V 	I

- 2 g. Sanders 2024: Adjusted for year and quarter of birth, ethnicity, socio-economic status or deprivation quintile, maternal age, gestational age, parity, maternal body mass index, birthweight, and concern identified by midwife before birth
- 3 h. Two-sided confidence interval calculated from one-sided confidence interval and odds ratio because the study reported one sided CI for these outcomes
- 4 i. Aughey 2021: Having water birth or giving birth in water vs. Not having water birth
- 5 j. Bovbjerg 2022: Under water birth vs. Unexposed to water birth
- 6 k. Aughey 2021: Adjusted for age, maternal BMI, parity, ethnicity, socio-economic status, and birthweight
- 7 I. Bovbjerg 2022: Adjusted for over 80 demographic and pregnancy risk covariables, including maternal age, parity, ethnicity, and socio-economic factors
- $8\,$ m. Risk difference used to analyse the double-arm zero-event study data
- 9 n. Absolute effect calculated based on risk difference

11

0. Serious indirectness because postpartum haemorrhage was defined as haemorrhage in 3 or 4th stage of labour, regardless of estimated blood loss

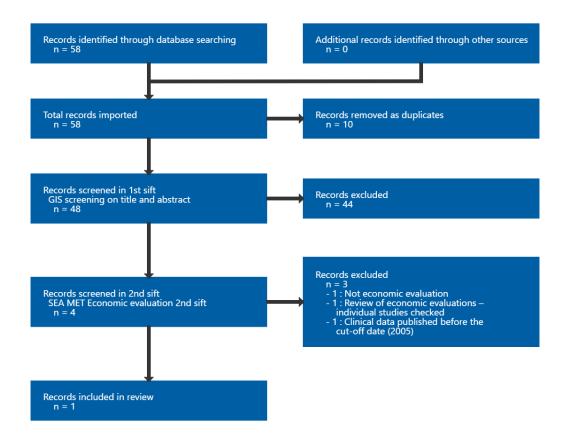
1 Appendix G - Economic evidence study selection

2 Figure 3: Economic evidence study selection flow chart

3

4

5



- 1 Appendix H Economic evidence tables
- 2 A.1 Water immersion during the second stage of labour versus
- 3 no water immersion during labour or standard care or water
- 4 immersion during the first stage only
- 5 **Poder, 2017**

Section	Details for Poder, 2017
Study details	Economic analysis type: Comparative cost analysis. Analysis design: Microsimulation using a decision tree Country setting: Canada Perspective: Quebec health network Time frame: Duration of childbirth Treatment duration: Duration of labour and childbirth Treatment effect duration: Duration of labour and childbirth Discount rate per year: NA (time horizon < 1 year)
Interventions	Intervention 1: No water immersion during labour and childbirth Intervention 2: Water immersion using pool Intervention 3: Water immersion using bath
Population	Population: Women during labour and childbirth Baseline characteristics: Simulation per each labouring woman based on a sample of 10,000 assuming a proportion of 0.25 women experiencing water immersion with a pool, 0.25 experiencing water immersion with a bath and 0.5 experiencing no water immersion. Base line data collected from systematic literature reviews Poder and Laviere (2014) and Cluett and Burns (2009)
Costs included	Original currency & cost year: 2014 Canadian dollars (presented here as 2014 UK pounds – converted using IMF purchasing power parities: https://eppi.ioe.ac.uk/costconversion/default.aspx)) Cost components incorporated: Analgesic requirements, duration of labour, perineal tears (not including episiotomies), costs associated with pool or bath and all associated costs (liner for a pool, cleaning and waterproof doppler costs), staffing costs of monitoring
Outcomes included	Primary health outcome(s) in economic analysis: Not included Key events modelled /analysed: None
Data Sources	Effectiveness data: Not included, study considers costs only Baseline / epidemiological data: Not included, study considers costs only Quality-of-life weights: NA Costs and/or resource use: Resource use informed by the literature reviews Poder and Laviere (2014) and Cluett and Burns (2009), costs

Section	Details for Poder, 2017
Coolion	were sourced from the hospital and physician tariffs by the Régied'assurance maladie du Québec.
Results: costs	Total costs (per patient): Presented at 2014 UK pounds Only the incremental costs compared with no water immersion were presented: Compared with no water immersion: Based on 5-hour labour duration and 10 percentage points less for epidural usage in the water birth group compared to no water immersion. Water pool: £100.93 (range based on range of pool cost £100.85 to £100.93) Water bath: £93.72 (range based on range of bath cost 95% CI: £93.72 to £97.13) Based on 5-hour labour duration and 5 percentage points less for epidural: Immersion using a pool: £109.13 Immersion using a bath: £101.92 7-hour labour duration and 5 percentage points less for epidural: Immersion using a Bath: £147.54 7-hour labour duration and 10 percentage points less for epidural: Immersion using a pool: £146.55 Immersion using a Bath: £139.34
Results: health outcomes	Not reported
Results: cost effectiveness	Not reported
Results: Uncertainty	Deterministic: Not reported Probabilistic: Average increased cost associated with waterbirth (assuming half use pool, half use bath) £124.54 (95% CI: £123.89 to £125.19)
Health inequalities assessment	NR
Comments	Source of funding: None Other: Did not include costs associated with hospital duration, which is an important opportunity cost to be omitted
Rating: Applicability	Partially applicable: Canadian healthcare system, only costs are included however it includes costs associated with perineal tears which is an outcome.

Section	Details for Poder, 2017
Rating: Quality/ limitations	Serious limitations: Does not include all relevant outcomes, only costs associated with perineal tears, does not include a measure of the newborn's health status nor does it include episiotomies or the duration of hospital stay. Costs associated with post-partum haemorrhage and neonatal admissions were not considered.

1 Abbreviations: CI= confidence interval; NA =not applicable; NR=not reported

1 Appendix I - Excluded studies

2 Effectiveness

3 Table 4: Studies excluded from the effectiveness review

Study	Code [Reason]
Allen, Jyai, Gao, Yu, Dahlen, Hannah et al. (2022) Is a randomized controlled trial of waterbirth possible? An Australian feasibility study. Birth (Berkeley, Calif.) 49(4): 697-708	- Study did not adjust for prespecified covariates: parity and ethnicity
Anonymous (2021) The effect of waterbirth on neonatal mortality and morbidity. Nursing & health sciences 23(2): 556-559	- Study design not relevant to this review protocol: Best Practice Information Sheet derived from a systematic review
Barry, Paula L, McMahon, Lean E, Banks, Ruth Am et al. (2020) Prospective cohort study of water immersion for labour and birth compared with standard care in an Irish maternity setting. BMJ open 10(12): e038080	- Study did not adjust for prespecified covariates: ethnicity
Baxter, L (2006) Research and education. What a difference a pool makes: making choice a reality. British Journal of Midwifery 14(6): 368-372	- Study did not adjust for prespecified covariates: maternal age, parity, and ethnicity
Bovbjerg, Marit L; Cheyney, Melissa; Everson, Courtney (2016) Maternal and Newborn Outcomes Following Waterbirth: The Midwives Alliance of North America Statistics Project, 2004 to 2009 Cohort. Journal of midwifery & women's health 61(1): 11-20	- Study did not adjust for prespecified covariates: maternal age and ethnicity
Bqlein, A.S. (2024) COMPREHENSIVE REVIEW OF LABOR PAIN MANAGEMENT, PERINEAL TEARS, AND EPISIOTOMY COMPLICATIONS: A FOCUS ON PREVENTION AND THE ROLE OF NURSES. New Armenian Medical Journal 18(3): 119	- Review article but not a systematic review: comprehensive review
Burns, Ethel E, Boulton, Mary G, Cluett, Elizabeth et al. (2012) Characteristics, interventions, and outcomes of women who used a birthing pool: a prospective observational study. Birth (Berkeley, Calif.) 39(3): 192-202	- Comparator in study does not match that specified in this review protocol: study compared different settings
Burns, Ethel, Feeley, Claire, Hall, Priscilla Jet al. (2022) Systematic review and meta-analysis to examine intrapartum interventions, and maternal and neonatal outcomes following immersion in water	- Systematic review, included studies checked for relevance: primary study that meets our inclusion criteria (Bailey 2020) is already included in our review

Intrapartum care – Water birth: second stage of labour: evidence review for water immersion during the second stage of labour DRAFT (August 2025) Page 65 of 85

Study	Code [Reason]
during labour and waterbirth. BMJ open 12(7): e056517	
Camargo, Joyce C S, Varela, Vitor, Ferreira, Fernanda M et al. (2018) The Waterbirth Project: Sao Bernardo Hospital experience. Women and birth: journal of the Australian College of Midwives 31(5): e325-e333	- Study design is not relevant to this review protocol: non comparative study
Cambaz, Zeynep and Solt Kirca, Ayca (2025) The Effect of Hydrotherapy Application on Pain During Birth and Postpartum Fatigue and Comfort. Journal of evaluation in clinical practice 31(3): e70060	- Study was conducted in Turkey, which is not an OECD high-income country
Campbell, Kimberley Ann (2008) The efficacy of water immersion during labour in reducing pain and enhancing personal control: a pilot study.	- master thesis
Carpenter, Jane; Burns, Ethel; Smith, Lesley (2022) Factors Associated With Normal Physiologic Birth for Women Who Labor In Water: A Secondary Analysis of A Prospective Observational Study. Journal of midwifery & women's health 67(1): 13-20	- Study did not adjust for prespecified covariates: ethnicity
Carregui-Vilar, Soledad, Moya-Artunedo, Eva M, Chalmeta, Ricardo et al. (2025) Epidural or water immersion? A prospective cohort study of maternal and neonatal outcomes in a tertiary hospital. Midwifery 146: 104392	- Study did not adjust for prespecified covariates: ethnicity
Centre Hospitalier Universitaire de Saint, Etienne (2023) Influence of Immersion in Water During Labor on the Request of Epidural Anesthesia by Pregnant Women. clinicaltrials.gov	- Not a peer-reviewed publication Study protocol registered on Clinicaltrials.gov
Chaillet, N., Belaid, L., Crochetiere, C. et al. (2014) Nonpharmacologic approaches for pain management during labor compared with usual care: A meta-analysis. Birth 41(2): 122	- Systematic review, included studies checked for relevance: studies were published before 2005
Cluett, E.R.; Burns, E.; Cuthbert, A. (2018) Immersion in water during labour and birth. Cochrane Database of Systematic Reviews 2018(5): cd000111	- Systematic review, included studies checked for relevance: studies were published before 2005 or conducted in low or middle income countries
Collins, Michelle R and Dahlgren- Roemmich, Dawn M (2013) Water immersion for labor and birth. Supporting a Physiologic Approach to Pregnancy and Birth: A Practical Guide: 157-172	- Review article but not a systematic review: narrative review

Study	Code [Reason]
Cortes, Eduardo; Basra, Ramandeep; Kelleher, Con J (2011) Waterbirth and pelvic floor injury: a retrospective study and postal survey using ICIQ modular long form questionnaires. European journal of obstetrics, gynecology, and reproductive biology 155(1): 27-30	- Study did not adjust for prespecified covariates: maternal age, parity, and ethnicity
Cristina, Taliento, Mara, Tormen, Arianna, Sabattini et al. (2022) Impact of waterbirth on post-partum hemorrhage, genital trauma, retained placenta and shoulder dystocia: A systematic review and meta-analysis. European journal of obstetrics, gynecology, and reproductive biology 276: 26-37	- Systematic review, included studies checked for relevance: primary studies that met our protocol inclusion criteria (Aughey 2021, Bailey 2020, Bovbjerg 2022) are already included in our review
Cunningham, Eileen (2016) Is water birth natural?. MIDIRS Midwifery Digest 26(1): 55-63	- Full text paper not available
Cunningham, Eileen (2016) Is water birth natural for the fetus?. MIDIRS Midwifery Digest 26(2): 203-208	- Full text paper not available
Dahlen, Hannah G, Dowling, Helen, Tracy, Mark et al. (2013) Maternal and perinatal outcomes amongst low risk women giving birth in water compared to six birth positions on land. A descriptive cross sectional study in a birth centre over 12 years. Midwifery 29(7): 759-64	- Study design is not relevant to this review protocol: cross-sectional study
Davies, Rowena, Davis, Deborah, Pearce, Melissa et al. (2015) The effect of waterbirth on neonatal mortality and morbidity: a systematic review and meta-analysis. JBI database of systematic reviews and implementation reports 13(10): 180-231	- Systematic review, included studies checked for relevance: studies were published before 2005 or did not adjust for prespecified covariates
De Angelis, Carlo, De Angelis, Chiara, Santangelo, Fabrizia et al. (2020) Immersion in water during labor and delivery. Perinatal Journal 28(3): 202-205	- Study design is not relevant to this review protocol: non-comparative study
De Camargo, J.C.S., Varela, V., Marcal Ferreira, F. et al. (2019) Perineal outcomes and its associated variables of water births versus non-water births: A cross-sectional study. Revista Brasileira de Saude Materno Infantil 19(4): 777	 Cohort study with <50 participants per arm: <50 participants in control group
Del Conte, Adam and Shah, Anuj (2021) Water immersion during labor and use of regional anesthesia: Does laboring in water reduce the number of patients requiring epidural anesthesia?. Evidence-Based Practice 24(3): 26-27	- Review article but not a systematic review: narrative review

Intrapartum care – Water birth: second stage of labour: evidence review for water immersion during the second stage of labour DRAFT (August 2025) Page 67 of 85

Study	Code [Reason]
Demirel, G, Celik, IH, Erdeve, O et al. (2013) Neonatal respiratory consequences from water birth in a tertiary centreJ Paediatr Child Health. 2012 May;48(5):419-23. Journal of Paediatrics & Child Health 49(1): e105-6	- Study design is not relevant to this review protocol: letter to the editor
Edwards, Sara, Angarita, Ana M, Talasila, Sahithi et al. (2024) Waterbirth: A Systematic Review and Meta-Analysis. American journal of perinatology 41(9): 1134-1142	- Systematic review, included studies checked for relevance: studies were published before 2005 or conducted in low-or middle-income countries
Ergin, Ayla, Asci, Ozlem, Bal, Meltem Demirgoz et al. (2024) The use of hydrotherapy in the first stage of labour: A systematic review and meta-analysis. International journal of nursing practice 30(1): e13192	- Systematic review, included studies checked for relevance: studies were published before 2005 or conducted in low-or middle-income countries or did not adjust for prespecified covariates
Fox, Deborah, Chu, Lina, Kelly, Er Li Ting et al. (2013) One-to-one midwifery care in Singapore the first 100 births. British Journal of Midwifery 21(10): 701-707	- Study design is not relevant to this review protocol: descriptive study
Gayiti, M-R-Y, Li, X-Y, Zulifeiya, A K et al. (2015) Comparison of the effects of water and traditional delivery on birthing women and newborns. European review for medical and pharmacological sciences 19(9): 1554-8	- Study was conducted in China, which is not an OECD high-income country
Gidaszewski, Beata, Khajehei, Marjan, Gibbs, Emma et al. (2019) Comparison of the effect of caseload midwifery program and standard midwifery-led care on primiparous birth outcomes: A retrospective cohort matching study. Midwifery 69: 10-16	- Intervention not relevant to this review protocol: compared effectiveness of different birth settings
Hakim, S., Santoso, B.I., Sungkar, A. et al. (2019) Controversial issue in water birth to reduce perineal trauma. Journal of South Asian Federation of Obstetrics and Gynaecology 11(3): 207	- Systematic review, included studies checked for relevance: studies were conducted in low- or middle-income countries or did not adjust for prespecified covariates
Halfdansdottir, Berglind, Ellinger-Kaya, Karianne, Fjosne, Kathrine et al. (2024) The association between waterbirth and perineal injury or other adverse outcomes among low-risk women with physiological birth: Results from the Nordic Home Birth Cohort Study. Women and birth: journal of the Australian College of Midwives 37(4): 101625	- Study did not adjust for prespecified covariates: maternal age and ethnicity
Haslinger, Christian, Burkhardt, Tilo, Stoiber, Bernhard et al. (2015) Position at birth as an important factor for the	- Comparator in study does not match that specified in this review protocol: study compared different positions at birth

Intrapartum care – Water birth: second stage of labour: evidence review for water immersion during the second stage of labour DRAFT (August 2025) Page 68 of 85

Study	Code [Reason]
occurrence of anal sphincter tears: a retrospective cohort study. Journal of perinatal medicine 43(6): 715-20	
Hautala, Maiju; Smeds, Marika; Taittonen, Leena (2022) Waterbirths were associated with low pain relief during delivery, high breastfeeding success and healthy newborn infants. Acta paediatrica (Oslo, Norway: 1992) 111(10): 1885-1890	- Study did not adjust for prespecified covariates: maternal age, parity, and ethnicity
Henderson, J., Burns, E.E., Regalia, A.L. et al. (2014) Labouring women who used a birthing pool in obsteric units in Italy: Prospective observational study. BMC Pregnancy and Childbirth 14(1): 17	- Study did not adjust for prespecified covariates: maternal age, parity and ethnicity
Herrero-Orenga, Carmen, Galiana, Laura, Sanso, Noemi et al. (2024) Effects of Water Immersion Versus Epidural as Analgesic Methods during Labor among Low-Risk Women: A 10-Year Retrospective Cohort Study. Healthcare (Basel, Switzerland) 12(19)	- Study did not adjust for prespecified covariates: maternal age, parity and ethnicity
Hodgson, Zoe G; Comfort, L Ruth; Albert, Arianne A Y (2020) Water Birth and Perinatal Outcomes in British Columbia: A Retrospective Cohort Study. Journal of obstetrics and gynaecology Canada: JOGC = Journal d'obstetrique et gynecologie du Canada: JOGC 42(2): 150-155	- Study did not adjust for prespecified covariate: maternal age, parity, and ethnicity
Holland, Ms Sari; Nagle, Cate; Smythe, OAM Wendy (2022) O40 - Togs on or Togs off? Perineal outcomes for women who birth in water compared to women who do notAustralian College of Midwives National Conference - Together at the Top, September 13-15, 2022, Cairns, Queensland, Australia. Women & Birth 35: npag-npag	- Conference abstract
Iglesias Casas, Susana, Perez-Fernandez, Maria Reyes, Montenegro-Alonso, Maria Sol et al. (2023) Neonatal outcomes after water birth: A retrospective cohort study. Enfermeria clinica (English Edition) 33(4): 292-302	- Study did not adjust for prespecified covariates: ethnicity
Jacoby, Susan, Becker, Gisela, Crawford, Susan et al. (2019) Water Birth Maternal and Neonatal Outcomes Among Midwifery Clients in Alberta, Canada, from 2014 to 2017: A Retrospective Study. Journal of obstetrics and gynaecology Canada: JOGC = Journal d'obstetrique et gynecologie du Canada: JOGC 41(6): 805-812	- Study did not adjust for prespecified covariates: maternal age, and ethnicity

Intrapartum care – Water birth: second stage of labour: evidence review for water immersion during the second stage of labour DRAFT (August 2025) Page 69 of 85

Study	Code [Reason]
Juda, W., Madej, M., Zalewski, M. et al. (2012) Personal experiences of water birth. Zdrowie Publiczne 122(3): 279	 Cohort study with <50 participants per arm: <50 participants in both water birth group and control group
Kacha, N., Dorel, G., Frappe, P. et al. (2024) Influence of water immersion on the use of epidural anesthesia during labor. Gynecologie Obstetrique Fertilite et Senologie 52(78): 454	- Study is not reported in English
Konieczka, Jagoda, Tomczyk, Katarzyna, Wilczak, Maciej et al. (2024) Factors Affecting Women's Assessment and Satisfaction with Their Childbirth. Medicina (Kaunas, Lithuania) 60(1)	- Study design is not relevant to this review protocol: cross-sectional study
Kubeczkova, Lenka, Kucerova Dankova, Jana, Prasivkova, Pavla et al. (2021) In water or on land? Evaluation of perinatal and neonatal outcomes of water births in low-risk women. Ceska gynekologie 86(5): 311-317	- Study is not reported in English
Kurvinen, Monna; Lamminpaa, Reeta; Vehvilainen-Julkunen, Katri (2025) Women's experiences of waterbirth: A systematic review with narrative synthesis. Midwifery 147: 104434	- Systematic review, included studies checked for relevance: studies were conducted in low or middle income countries or did not adjust for prespecified covariates or were qualitative studies
Kvach, E. and Martonffy, A.I. (2012) Are there any risks to a water birth?. Evidence-Based Practice 15(4): 13	- Review article but not a systematic review: narrative review
Lanier, Ariel L, Wiegand, Samantha L, Fennig, Kathleen et al. (2021) Neonatal Outcomes After Delivery in Water. Obstetrics and gynecology 138(4): 622-626	- Study did not adjust for prespecified covariates: maternal age, parity, and ethnicity
Lathrop, Anthony; Bonsack, Carrie F; Haas, David M (2018) Women's experiences with water birth: A matched groups prospective study. Birth (Berkeley, Calif.) 45(4): 416-423	- Study did not adjust for prespecified covariates: maternal age, parity, and ethnicity, and did not clearly state whether participants had low-risk or intermediate-risk or high-risk pregnancies
	- Population is not relevant to this review protocol: study did not clearly state whether participants had low-risk or intermediate-risk or high-risk pregnancies
Leask Capitulo, Kathleen (2016) A Comparison of Maternal and Neonatal Outcomes Between Water Immersion During Labor and Conventional Labor and Delivery. MCN: The American Journal of Maternal Child Nursing 41(1): 66-66	- Study was conducted in China, which is not an OECD high-income country

Study	Code [Reason]
Lewis, Lucy, Hauck, Yvonne L, Butt, Janice et al. (2018) Obstetric and neonatal outcomes for women intending to use immersion in water for labour and birth in Western Australia (2015-2016): A retrospective audit of clinical outcomes. The Australian & New Zealand journal of obstetrics & gynaecology 58(5): 539-547	- Study did not adjust for prespecified covariates: maternal age and ethnicity
Lewis, Lucy, Hauck, Yvonne L, Crichton, Caroline et al. (2018) The perceptions and experiences of women who achieved and did not achieve a waterbirth. BMC pregnancy and childbirth 18(1): 23	- No relevant protocol outcomes reported
Lim, Karen M X; Tong, Pearl S Y; Chong, Yap-Seng (2016) A comparative study between the pioneer cohort of waterbirths and conventional vaginal deliveries in an obstetrician-led unit in Singapore. Taiwanese journal of obstetrics & gynecology 55(3): 363-7	- Study did not adjust for prespecified covariates: adjust for ethnicity
Liu, Yinglin, Liu, Yukun, Huang, Xiuzhi et al. (2014) A comparison of maternal and neonatal outcomes between water immersion during labor and conventional labor and delivery. BMC pregnancy and childbirth 14: 160	- Study was conducted in China, which is not an OECD high-income country
Lodge, F. and Haith-Cooper, M. (2016) The effect of maternal position at birth on perineal trauma: A systematic review. British Journal of Midwifery 24(3): 172	- Systematic review, included studies checked for relevance: studies were published before 2005 or did not adjust for prespecified covariates
Lucena da Silva, M., Andressa Bastos Primo de Sousa Santos, T., Wane Carvalho Leite, L. et al. (2023) The effectiveness of interventions in the prevention of perineal trauma in parturients: A systematic review with meta-analysis. European Journal of Obstetrics and Gynecology and Reproductive Biology 283: 100	- Systematic review, included studies checked for relevance: studies conducted in low- or middle-income countries
Lukasse, Mirjam, Rowe, Rachel, Townend, John et al. (2014) Immersion in water for pain relief and the risk of intrapartum transfer among low risk nulliparous women: secondary analysis of the Birthplace national prospective cohort study. BMC pregnancy and childbirth 14: 60	- Study did not contain an intervention relevant to this review protocol: Participants used immersion in water for pain relief, and it was unclear whether immersion was during the second stage of labour
Malarewicz, A, Wydrzynski, G, Szymkiewicz, J et al. (2005) The influence of water immersion on the course of first stage of parturition in primiparous women. Medycyna wieku rozwojowego 9(4): 773- 780	- Full text paper not available

Intrapartum care – Water birth: second stage of labour: evidence review for water immersion during the second stage of labour DRAFT (August 2025) Page 71 of 85

Study	Code [Reason]
Mallen-Perez, Laura, Roe-Justiniano, M Teresa, Colome Ochoa, Nuria et al. (2018) Use of hydrotherapy during labour: Assessment of pain, use of analgesia and neonatal safety. Enfermeria clinica (English Edition) 28(5): 309-315	- Study is not reported in English
Marin, N.V., Ambit, G.C., Sanchez-Garcia, J.C. et al. (2024) Complementary techniques of relaxation and non-pharmacological analgesia during childbirth: systematic review. Enfermeria Global 23(1): 475	- Systematic review, included studies checked for relevance: studies did not report our outcomes of interest
Martinez-Galiano, J.M. (2018) Labour pain management with water immersion. West Indian Medical Journal 67(1): 46	- Study design is not relevant to this review protocol: non-comparative study (single group study)
Maude, Robyn M and Kim, Mikyung (2020) Getting into the water: a prospective observational study of water immersion for labour and birth at a New Zealand District Health Board. BMC pregnancy and childbirth 20(1): 312	- Study design is not relevant to this review protocol: non-comparative study (single group study)
McKinney, Jordan A, Vilchez, Gustavo, Jowers, Alicia et al. (2024) Water birth: a systematic review and meta-analysis of maternal and neonatal outcomes. American journal of obstetrics and gynecology 230(3s): 961-s979e33	- Systematic review, included studies checked for relevance: primary studies that met our protocol inclusion criteria (Aughey 2021, Bailey 2020) are already included in our review
Mellado-Garcia, Elena, Diaz-Rodriguez, Lourdes, Cortes-Martin, Jonathan et al. (2024) Effects of Hydrotherapy on the Management of Childbirth and Its Outcomes-A Retrospective Cohort Study. Nursing reports (Pavia, Italy) 14(2): 1251- 1259	- Study did not adjust for prespecified covariates: maternal age, parity, and ethnicity (for outcomes of interest adjusted estimates are not reported)
Mellado-Garcia, Elena, Diaz-Rodriguez, Lourdes, Cortes-Martin, Jonathan et al. (2024) Systematic Reviews and Synthesis without Meta-Analysis on Hydrotherapy for Pain Control in Labor. Healthcare (Basel, Switzerland) 12(3)	- Systematic review, included studies checked for relevance: studies were published before 2005 or conducted in low or middle income countries or did not adjust for prespecified covariates or were qualitative studies
Mellado-Garcia, Elena, Diaz-Rodriguez, Lourdes, Cortes-Martin, Jonathan et al. (2024) Comparative Analysis of Therapeutic Showers and Bathtubs for Pain Management and Labor Outcomes-A Retrospective Cohort Study. Journal of clinical medicine 13(12)	- Cohort study with <50 participants per arm: <50 participants in control group
Mellado-Garcia, Elena, Diaz-Rodriguez, Lourdes, Cortes-Martin, Jonathan et al. (2024) Hydrotherapy in Pain Management	- Systematic review, included studies checked for relevance: included studies

Intrapartum care – Water birth: second stage of labour: evidence review for water immersion during the second stage of labour DRAFT (August 2025) Page 72 of 85

Study	Code [Reason]
in Pregnant Women: A Meta-Analysis of Randomized Clinical Trials. Journal of clinical medicine 13(11)	published before 2005 and studies from middle income countries
Mellado-Garcia, Elena, Diaz-Rodriguez, Lourdes, Cortes-Martin, Jonathan et al. (2023) Safety and Effect of the Use of Hydrotherapy during Labour: A Retrospective Observational Study. Journal of clinical medicine 12(17)	- Study does not contain an intervention relevant to this review protocol: water immersion only in the first stage of labour
Menakaya, Uche, Albayati, Shakeeba, Vella, Elizabeth et al. (2013) A retrospective comparison of water birth and conventional vaginal birth among women deemed to be low risk in a secondary level hospital in Australia. Women and birth: journal of the Australian College of Midwives 26(2): 114-8	- Study did not adjust for prespecified covariates: ethnicity
Meyer, Shaunette Lin (2018) Neonatal Cardiovascular, Respiratory, and Thermal Transition in the First Four Hours After Water Birth Compared to Water Labor and No Immersion. Neonatal Cardiovascular, Respiratory & Thermal Transition In The First Four Hours After Water Birth Compared To Water Labor & No Immersion: 1-1	- Not a peer-reviewed publication It is a PhD dissertation or thesis
Montiel-Morales, Diana Patricia; Ferreira- Jaime, Fernando; Rendón-Macías, Mario Enrique (2017) Comparisson of the transition period in newborn delivered by water-birth versus land-birth. Cohort study. Revista Mexicana de Pediatría 83(5): 148- 153	- Study is not reported in English
Neiman, Emily, Austin, Elizabeth, Tan, Alai et al. (2020) Outcomes of Waterbirth in a US Hospital-Based Midwifery Practice: A Retrospective Cohort Study of Water Immersion During Labor and Birth. Journal of midwifery & women's health 65(2): 216-223	- Study did not adjust for prespecified covariates: ethnicity
Nutter, Elizabeth, Meyer, Shaunette, Shaw-Battista, Jenna et al. (2014) Waterbirth: an integrative analysis of peer-reviewed literature. Journal of midwifery & women's health 59(3): 286-319	- Systematic review, included studies checked for relevance: a potential study (Torrisi 2010) that was not picked up by our search was added to EPPI
Pagano, Eva, De Rota, Barbara, Ferrando, Alberto et al. (2010) An economic evaluation of water birth: the cost-effectiveness of mother well-being. Journal of evaluation in clinical practice 16(5): 916-9	- Study did not report outcomes relevant to this review, and did not adjust for prespecified covariates

Study	Code [Reason]
Papoutsis, Dimitrios, Antonakou, Angeliki, Gornall, Adam et al. (2021) The Incidence of and Predictors for Severe Perineal Trauma and Intact Perineum in Women Having a Waterbirth in England: A Hospital-Based Study. Journal of women's health (2002) 30(5): 681-688	- Study did not adjust for prespecified covariates: maternal age, parity, and ethnicity (analysis of our outcomes of interest were not adjusted for these prespecified covariates)
Peacock, Phil J, Zengeya, Stanley T, Cochrane, Lesley et al. (2018) Neonatal Outcomes Following Delivery in Water: Evaluation of Safety in a District General Hospital. Cureus 10(2): e2208	- Study did not adjust for prespecified covariates: maternal age, parity, and ethnicity
Poder, TG and Larivière, M (2014) Advantages and disadvantages of water birth. A systematic review of the literature. GYNECOLOGIE OBSTETRIQUE & FERTILITE 42(10): 706-713	- Study is not reported in English
Preston, Helen Louise, Alfirevic, Zarko, Fowler, Gillian Elizabeth et al. (2019) Does water birth affect the risk of obstetric anal sphincter injury? Development of a prognostic model. International urogynecology journal 30(6): 909-915	- Study did not adjust for prespecified covariates: maternal age
Rodriguez Gesteira, C. and Soto Gonzalez, M. (2021) Maternal and neonatal effects of water birth. A systematic review. Clinica e Investigacion en Ginecologia y Obstetricia 48(1): 44	- Study is not reported in English
Sanders, Julia, Barlow, Christy, Brocklehurst, Peter et al. (2025) Characteristics of Women, Intrapartum Interventions, and Maternal and Neonatal Outcomes Among Users of Intrapartum Water Immersion: The UK POOL Cohort Study. Birth (Berkeley, Calif.)	- Secondary publication of the POOL study (Sanders 2024) that does not provide any additional relevant information
Seed, Emma, Kearney, Lauren, Weaver, Edward et al. (2023) A prospective cohort study comparing neonatal outcomes of waterbirth and land birth in an Australian tertiary maternity unit. The Australian & New Zealand journal of obstetrics & gynaecology 63(1): 59-65	- Study did not adjust for prespecified covariates: parity and ethnicity
Sert, Umit Yasemin, Ozel, Sule, Neselioglu, Salim et al. (2020) Water Immersion During the Labour and Effects on Oxidative Stress. Fetal and pediatric pathology 39(3): 185-193	- Study was conducted in Turkey, which is not an OECD high-income country
Shaw-Battista, J. (2017) Systematic Review of Hydrotherapy Research. Journal of Perinatal and Neonatal Nursing 31(4): 303	- Systematic review, included studies checked for relevance: studies were

Intrapartum care – Water birth: second stage of labour: evidence review for water immersion during the second stage of labour DRAFT (August 2025) Page 74 of 85

Study	Code [Reason]
	published before 2005 or conducted in low or middle income countries
Shaw-Battista, JC (2009) Optimal outcomes of labor and birth in water compared to standard maternity care. Optimal Outcomes of Labor & Birth in Water Compared to Standard Maternity Care: 356p-356p	- Not a peer-reviewed publication: It is PhD dissertation or thesis
Shaw-Battista, Jenna (2017) Systematic Review of Hydrotherapy Research: Does a Warm Bath in Labor Promote Normal Physiologic Childbirth?. The Journal of perinatal & neonatal nursing 31(4): 303-316	- Review article but not a systematic review: European Conformity Testing Document
Sia Jonsdottir, Sigridur (2014) Immersion in Water for Pain Relief and the Risk of Intrapartum Transfer Among Low Risk Nulliparous Women: Secondary Analysis of the Birthplace National Prospective Cohort Study. MCN: The American Journal of Maternal Child Nursing 39(4): 274-274	- Study does not contain an intervention relevant to this review protocol: participants used immersion in water for pain relief, and it was unclear whether immersion was during the second stage of labour
Sidebottom, Abbey C, Vacquier, Marc, Simon, Kathrine et al. (2019) Who Gives Birth in the Water? A Retrospective Cohort Study of Intended versus Completed Waterbirths. Journal of midwifery & women's health 64(4): 403-409	- Study did not report outcomes relevant to this review, and did not adjust for prespecified covariates (maternal age, parity, ethnicity, birthweight, and socioeconomic status)
Sidebottom, Abbey C, Vacquier, Marc, Simon, Kathrine et al. (2020) Maternal and Neonatal Outcomes in Hospital-Based Deliveries With Water Immersion. Obstetrics and gynecology 136(4): 707-715	- Study did not adjust for prespecified covariates: age, parity and ethnicity, and there are differences between groups
Simpson, Kathleen Rice (2013) Underwater birth. Journal of obstetric, gynecologic, and neonatal nursing: JOGNN 42(5): 588-94	- Systematic review, included studies checked for relevance: included studies published before 2005 and studies from middle income countries
Snapp, Carol, Stapleton, Susan Rutledge, Wright, Jennifer et al. (2020) The Experience of Land and Water Birth Within the American Association of Birth Centers Perinatal Data Registry, 2012-2017. The Journal of perinatal & neonatal nursing 34(1): 16-26	- Study did not adjust for prespecified covariates: maternal age, parity, and ethnicity
Taylor, H., Kleine, I., Bewley, S. et al. (2016) Neonatal outcomes of waterbirth: A systematic review and meta-analysis. Archives of Disease in Childhood: Fetal and Neonatal Edition 101(4): f357	- Systematic review, included studies checked for relevance: a potential study (Thoni 2010) that was not picked up by search was added to EPPI
Thoeni, A; Ploner, F; Zech, N (2008) Water contamination and the rate of infections for	- Population not relevant to this review protocol

Study	Code [Reason]
water births. Open Women's Health Journal 2: 5-10	Study did not clearly state whether participants had term pregnancy or low-risk or intermediate-risk or high-risk pregnancies
Thoeni, A, Zech, N, Moroder, L et al. (2005) Review of 1600 water births. Does water birth increase the risk of neonatal infection?. The journal of maternal-fetal & neonatal medicine: the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians 17(5): 357-61	- Study did not adjust for prespecified covariates: maternal age, parity and ethnicity
Thoni A, Mussner K PF (2010) Water birthing: Retrospective review of 2625 water births. Contamination of birth pool water and risk of microbial cross-infection. Minerva ginecologica 62(3): 203-11	- Study is not reported in English
Thoni, A., Zech, N., Ploner F (2007) Giving birth in the water: experience after 1,825 water deliveries. Retrospective descriptive comparison of water birth and traditional delivery methods. Gynakol Geburtshilfliche Rundsch 47: 76-80	- Study is not reported in English
Torrisi G, Giuseppe E, Fonti I, Ferraro S, D'Urso E GV (2010) Water birth and perineal dysfunctions: Prospective study. Neurourol Urodyn 29 (S2): 89-91	- Study did not report outcomes relevant to this review, and did not adjust for prespecified covariates
Uccella, Stefano, Manzoni, Paolo, Militello, Maria A et al. (2024) Neonatal Outcomes of Water Delivery versus Land Delivery: A Retrospective Propensity Score Weighted Study. American journal of perinatology 41(s01): e1775-e1782	- Study did not adjust for prespecified covariates: parity and ethnicity
Ulfsdottir, Hanna, Saltvedt, Sissel, Edqvist, Malin et al. (2022) Management of the active second stage of labor in waterbirths compared with conventional births - a prospective cohort study. Midwifery 107: 103283	- Study did not adjust for prespecified covariates: maternal age and ethnicity
Ulfsdottir, Hanna; Saltvedt, Sissel; Georgsson, Susanne (2019) Women's experiences of waterbirth compared with conventional uncomplicated births. Midwifery 79: 102547	- Study did not adjust for prespecified covariates: maternal age, parity, and ethnicity
Ulfsdottir, Hanna; Saltvedt, Sissel; Georgsson, Susanne (2018) Waterbirth in Sweden - a comparative study. Acta obstetricia et gynecologica Scandinavica 97(3): 341-348	- Study did not adjust for prespecified covariates: ethnicity

Intrapartum care – Water birth: second stage of labour: evidence review for water immersion during the second stage of labour DRAFT (August 2025) Page 76 of 85

Study	Code [Reason]
Vanderlaan, Jennifer (2017) Retrospective Cohort Study of Hydrotherapy in Labor. Journal of obstetric, gynecologic, and neonatal nursing: JOGNN 46(3): 403-410	- Study did not report outcomes relevant to this review
Vanderlaan, Jennifer; Hall, Priscilla J; Lewitt, MaryJane (2018) Neonatal outcomes with water birth: A systematic review and meta-analysis. Midwifery 59: 27- 38	- Systematic review, included studies checked for relevance: a potential study (Thoni 2007) that was not picked up by our search was added to EPPI
Wu, M., Jin, W., Chen, S. et al. (2018) Maternal and perinatal outcomes among low risk women giving birth in water: A retrospective study in a maternity & infant health hospital over 7 years. International Journal of Clinical and Experimental Medicine 11(2): 1318	- Study was conducted in China, which is not an OECD high-income country
Yorganci, Aycag, Buyuk, Gul Nihal, Akyol, Mesut et al. (2021) The Effects of Water Immersion during First Stage of Labor on Postpartum Systemic Inflammatory Response. Zeitschrift für Geburtshilfe und Neonatologie 225(3): 251-256	- Study was conducted in Turkey, which is not an OECD high-income country
Yun, Zhao, Mei, Xiao, Fei, Tang et al. (2017) The effect of water immersion delivery on the strength of pelvic floor muscle and pelvic floor disorders during postpartum period: An experimental study. Medicine 96(41): 1-6	- Study was conducted in China, which is not an OECD high-income country
Zachariah, R R, Forst, S, Hodel, N et al. (2024) Is water delivery a good idea to prevent obstetric anal sphincter injuries in low risk primiparae? An exploratory study in a Swiss public teaching hospital. European journal of obstetrics, gynecology, and reproductive biology 294: 39-42	- Study did not adjust for prespecified covariates: maternal age, parity, and ethnicity
Zanetti-Daellenbach, Rosanna A, Tschudin, Sibil, Zhong, Xiao Yan et al. (2007) Maternal and neonatal infections and obstetrical outcome in water birth. European journal of obstetrics, gynecology, and reproductive biology 134(1): 37-43	- Study did not adjust for prespecified covariates: maternal age, parity, and ethnicity
Zanetti-Dallenbach, R A; Holzgreve, W; Hosli, I (2007) Neonatal group B streptococcus colonization in water births. International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics 98(1): 54-5	- Population not relevant to this review protocol Study did not clearly state whether participants had term pregnancy or low-risk or intermediate-risk or high-risk pregnancies

Study	Code [Reason]
Zanetti-Dallenbach, R., Lapaire, O., Holzgreve, W. et al. (2007) Neonatal colonization-rate with group B streptococcus is lower in neonates born underwater than after conventional vaginal delivery. Geburtshilfe und Frauenheilkunde 67(10): 1114	- Study did not adjust for prespecified covariates: maternal age, parity, and ethnicity
Zanetti-Dallenbach, Rosanna, Lapaire, Olav, Maertens, Anne et al. (2006) Water birth, more than a trendy alternative: a prospective, observational study. Archives of gynecology and obstetrics 274(6): 355-65	- Study did not adjust for prespecified covariates: maternal age, parity, and ethnicity
Zhang, Guanran and Yang, Qiuhong (2022) Comparative Efficacy of Water and Conventional Delivery during Labour: A Systematic Review and Meta-Analysis. Journal of healthcare engineering 2022: 7429207	-This article was retracted by authors
Zhao, Yun, Xiao, Mei, Tang, Fei et al. (2017) The effect of water immersion delivery on the strength of pelvic floor muscle and pelvic floor disorders during postpartum period: An experimental study. Medicine 96(41): e8124	-Study was conducted in China, which is not an OECD high-income country
Ziolkowski, R., Dabrus, D., Czerniawski, W. et al. (2009) An assessment of water births based on the author's own research. Ginekologia i Poloznictwo 14(4): 57	- Full text paper not available

Abbreviations: An OECD high-income country: a country which is a member of the Organisation for Economic Co-operation and Development and also has a high gross national income per capita, as defined by the World Bank

Economic

6 Table 5: Studies excluded from the economic review

Study	Reason for exclusion
Malaysian Health Technology Assessment, (MaHTAS) (2013)	- Review of economic evaluations – individual studies checked
Water birth.	The only cost-effectiveness evidence within this paper is summarising Pagano 2010 which has been extracted separately.
Pagano, Eva, De Rota, Barbara, Ferrando, Alberto et al. (2010) An	- Clinical data published before the cut-off date (2005)
economic evaluation of water birth: the cost-effectiveness of mother well- being. Journal of evaluation in	- Retrospective study design
clinical practice 16(5): 916-9	

Intrapartum care – Water birth: second stage of labour: evidence review for water immersion during the second stage of labour DRAFT (August 2025) Page 78 of 85

Study	Reason for exclusion
Papoutsis, D. (2023) Waterbirth A simple and cost-effective way to promote normality in childbirth. Archives of Hellenic Medicine 40(4): 564	- Not economic evaluation

Appendix J - Methods

1

- 2 This evidence review was developed using the methods and process
- described in <u>Developing NICE guidelines: the manual</u>. Methods specific to this
- 4 review question are outlined below.

5 Methods for combining studies

- 6 Meta-analysis was performed where there was no significant variation
- 7 between studies or extremely serious heterogeneity (1²≥80%). The POOL
- 8 study included in this review is a non-inferiority study, which was not designed
- 9 to investigate whether an intervention is superior to an existing one or a
- standard care (Sanders 2024). The results of non-inferiority studies may not
- 11 match those of other cohort studies, so this study was not pooled with other in
- the review. This study also reported superiority analysis for perineal trauma,
- with outcomes presented separately for nulliparous and multiparous women.
- 14 As other studies in the review did not report outcomes by parity, these results
- 15 could not be pooled.

16 Assessing imprecision

- 17 Using the optimal information size (OIS) approach recommended by GRADE
- 18 <u>Guidance 34</u>, imprecision in dichotomous outcomes reported as risk ratio
- 19 (RR) and odds ratio (OR) was evaluated based on the ratio of the upper to the
- 20 lower boundary of the confidence interval (CI). A ratio greater than 3 for RR or
- 21 greater than 2.5 for OR was considered very seriously imprecise. This was
- 22 used to determine whether to downgrade twice for imprecision.
- No continuous outcomes were reported in this review.

24 Assessing clinical importance

- 25 For this review, there were no published, consensus based or commonly
- 26 accepted minimally important differences (MIDs) available for any of the
- outcomes, nor were any identified by the guideline committee (GC). The GC
- agreed that all outcomes are serious outcomes, therefore they decided to use

2	used the following decision rules to assess clinical importance:
3	(1) Evidence of benefit (EV. OF BENEFIT): where the point estimate is
4	less than 1 (which is the null value for RRs and ORs) and the 95%
5	CI does not include 1, indicating a statistically significant reduction
6	in the outcome compared to the comparison group.
7	(2) Evidence of disbenefit (EV. OF DISBENEFIT): where the point
8	estimate is greater than 1 and the 95% CI does not include 1,
9	indicating a statistically significant increase in the outcome
10	compared to the comparison group.
11	(3) Uncertain effect (UN. EFFECT): where the point estimate is less
12	than or greater than 1 and the 95% CI includes 1, indicating no
13	statistically significant difference between groups.
14	(4) Evidence of no effect (EV. OF NO EFFECT): where the point
15	estimate is 1 and the 95% CI includes 1, indicating no statistically
16	significant difference between groups.
17	Note: The above categories are based on positive outcomes (i.e.,
18	where a large Point Estimate indicates better outcome). If outcomes
19	are negative (i.e., where a large Point Estimate indicates worse
20	outcome), then whether an intervention is considered to have a benefit
21	or disbenefit should be switched.
22	Informative statements
23	Informative statements were developed by considering both clinical
24	importance and the certainty of the evidence. They were adapted from
25	GRADE Guidance 26.
26 27 28	An example of how these statements were drafted is provided in the table below.

statistical significance to assess clinical importance. For all outcomes, we

(clinical importance)	(replace X with intervention, replace 'reduce/increase' with direction of effect, replace 'outcome' with name of outcome, replace Y with name of comparator).	
HIGH Certainty of the evid	ence (GRADE)	
Effect (Evidence of benefit or disbenefit)	The evidence shows that X reduces/increases [outcome] compared to Y.	
Trivial, small unimportant effect or no effect (Evidence of no effect)	The evidence shows that X results in little to no difference in [outcome] compared to Y.	
MODERATE Certainty of the	he evidence	
Effect (Evidence of benefit or disbenefit)	The evidence shows that X probably reduces/increases [outcome] compared to Y.	
Trivial, small unimportant effect or no effect (Evidence of no effect or uncertain effect)	The evidence shows that X probably results in little to no difference in [outcome] compared to Y.	
LOW Certainty of the evidence	ence	
Effect (Evidence of benefit or disbenefit)	The evidence suggests X may reduce/increase [outcome] compared to Y.	
Trivial, small unimportant effect or no effect (Evidence of no effect)	The evidence suggests that X results in little to no difference in [outcome] compared to Y.	
Uncertain effect	The evidence is very uncertain about the effect of X on [outcome] compared to Y.	
VERY LOW Certainty of th	VERY LOW Certainty of the evidence	
Any effect	The evidence is very uncertain about the effect of X on [outcome] compared to Y.	

Abbreviations: GRADE: Grading of Recommendations Assessment, Development

2 and Evaluation

3

- 4 <u>Calculation of 2-sided confidence interval (CI) for effect estimates</u>
- 5 For some outcomes in this review, studies only reported effect estimates with
- 6 a one-sided confidence interval (CI). These were converted to two-sided CIs
- 7 using the following method:
- (1) Calculating upper bound of two-sided 95% CI from one-sided 95% CI
 (upper bound) and OR
- Calculate the standard error (SE) of the log odds ratio (log OR):
 SE of log OR = (log(Upper bound) log (OR)) /1.6448
- Find the upper bound for the 2 sided 95% CI (on the log scale):

 Upper bound on log scale = log (mean OR) + (SE of logORX1.96)

2	Upper bound as OR = exp(upper bound on log scale)
3	(2) Calculating lower bound of two-sided 95% CI from one-sided 95% CI (upper bound) and OR
5 6	 Calculate the standard error (SE) of the log odds ratio (log OR): SE of log OR = (log(Upper bound) – log (OR))/1.6448
7 8	 Find the lower bound for the 2 sided 95% CI (on the log scale): Lower bound on log scale = log (mean OR) - (SE of logORX1.96)
9	 Convert the lower bound back to the OR scale:
10	Lower bound as OR = exp(lower bound on log scale)
11	This allowed all results to be assessed in the same way.
12	Use of Artificial Intelligence in drafting the committee discussion and
13	interpretation of the evidence section of the evidence report
14	Artificial intelligence (AI) was used to generate the initial drafts of the 'benefits
15	and harms' and 'cost effectiveness and resource use' sections of the
16	committee discussion and interpretation of the evidence (CDE). It was not
17	used for drafting the 'outcomes that matter most' and 'quality of the evidence'
18	sections. The transcript from the committee meeting, the recommendation
19	made by the committee and the prompt to extract relevant information were
20	uploaded into the AI tool. This information was used by the AI tool to generate
21	an initial draft of the CDE which was then edited and refined by the technical
22	team who attended the committee meeting. Any risk of inaccuracy in the
23	summary prepared by the AI tool was mitigated by human oversight by the
24	technical team who reviewed and amended the CDE, based on their
25	knowledge from the committee meeting discussion and the evidence, to
26	generate the final draft. The committee also reviewed the draft and agreed it
27	was an accurate representation of the discussion.

• Convert the upper bound back to the OR scale:

1

- 1 Sanders, Julia, Barlow, Christy, Brocklehurst, Peter et al. (2024) Maternal and
- 2 neonatal outcomes among spontaneous vaginal births occurring in or out of
- 3 water following intrapartum water immersion: The POOL cohort study. BJOG:
- 4 an international journal of obstetrics and gynaecology 131(12): 1650-1659

1	Appendix K - Research recommendations
2	No research recommendations were made for this review question.
3	·
3	