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RESEARCH ARTICLE

Maternal and neonatal outcomes among spontaneous vaginal births occurring in or out of water following intrapartum water immersion: The POOL cohort study

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Abstract

Objective: Warm water immersion during labour provides women with analgesia and comfort. This cohort study aimed to establish among women using intrapartum water immersion analgesia, without antenatal or intrapartum risk factors, whether waterbirth is as safe for them and their babies as leaving the water before birth.

Design: Cohort study with non-inferiority design.

Setting: Twenty-six UK NHS maternity services.

Sample: A total of 73 229 women without antenatal or intrapartum risk factors, using intrapartum water immersion, between 1 January 2015 and 30 June 2022. The analysis excluded 12 827 (17.5%) women who received obstetric or anaesthetic interventions before birth.

Methods: Non-inferiority analysis of retrospective and prospective data captured in NHS maternity and neonatal information systems.

Main outcome measures: Maternal primary outcome: obstetric anal sphincter injury (OASI) by parity; neonatal composite primary outcome: fetal or neonatal death, neonatal unit admission with respiratory support or administration of antibiotics within 48 hours of birth.

Results: Rates of the primary outcomes were no higher among waterbirths compared with births out of water: rates of OASI among nulliparous women (waterbirth: 730/15 176 [4.8%] versus births out of water: 641/12 210 [5.3%]; adjusted odds ratio [aOR] 0.97, one-sided 95% CI, −∞ to 1.08); rates of OASI among parous women (waterbirth: 269/24 451 [1.1%] versus births out of water 144/8565 [1.7%]; aOR 0.64, one-sided 95% CI −∞ to 0.78) and rates of the composite adverse outcome among babies (waterbirth 263/9868 [2.7%] versus births out of water 224/5078 [4.4%]; aOR 0.65, one-sided 95% CI −∞ to 0.79).

Conclusion: Among women using water immersion during labour, remaining in the pool and giving birth in water was not associated with an increase in the incidence of adverse primary maternal or neonatal outcomes.

KEYWORDS
labour, neonatal morbidity, perineal trauma, waterbirth

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1 | INTRODUCTION

Since 2007 the National Institute for Health and Care Excellence (NICE) has recommended that women without pregnancy risk factors should be offered water immersion for analgesia during labour.[1–3] Some women using water immersion leave the pool before birth either through choice or to receive additional clinical care, others remain in the water for birth, known as waterbirth. There have been case reports of adverse neonatal outcomes following waterbirth including water inhalation, sepsis and cord avulsion,[4] other reports have suggested an increased rate of maternal obstetric anal sphincter injury (OASI) occurring during waterbirths.[5] NICE considers there to be insufficient high-quality evidence to either support or discourage giving birth in water.

Large-scale randomised clinical trials (RCT) of waterbirth have not been conducted. The largest study to assess the feasibility of conducting an adequately powered non-inferiority RCT or cohort study comparing outcomes among waterbirths with those for births out of water concluded that a cohort study, but not an RCT, was feasible. The study recruited 1260 women during late pregnancy, of whom 15% ($n = 188$) indicated that randomisation would be acceptable to them. Among the 1260 participants, 550 remained eligible at the onset of the second stage of labour and 303 waterbirths were included in the final analysis.[6]

Several cohort studies and a recent systematic review[7] have reported outcomes of waterbirths without finding an excess in maternal or neonatal morbidity following birth in water. These studies reported outcomes for out of hospital births outside the UK[8]; were of insufficient size to explore rare but important outcomes[9]; or compared outcomes between births in water with spontaneous vaginal births at term out of water, including births following interventions such as Syntocinon augmentation of labour or epidural analgesia.[10]

The primary objective of this study was to answer a question commonly asked by women using water immersion analgesia, that is 'if everything remains OK during labour, should I stay in or get out for birth?' The study was designed to establish, among women who used intrapartum water immersion and where pregnancy and labour were uncomplicated, whether giving birth in water was as safe for mothers and their babies as leaving the water before birth.

2 | METHODS

This was a non-inferiority observational cohort study using retrospective and prospective data captured in electronic maternity and neonatal information systems.

2.1 | Setting and participants

Maternity services were eligible to participate if they used the Euroking maternity information system, a system commonly used by maternity services throughout England. All 26 eligible sites in England and Wales participated.

Women were included in the primary analysis if under guidance from NICE they did not have antenatal or intrapartum factors indicating that birth in an obstetric unit should be recommended (Table S1a–e).[11] Women were also excluded from the primary analysis if they received obstetric or anaesthetic interventions before birth, including operative or instrumental birth, Syntocinon for augmentation of labour, continuous electronic fetal heart rate monitoring or administration of epidural analgesia. Where complications, such as a fetal bradycardia, became apparent only once spontaneous vaginal birth was imminent, women remained in the primary analysis.

Births in which the fetus was partially born into water, including in the event of shoulder dystocia or a previously unrecognised breech presentation, remained in the waterbirth group even if the birth was completed out of water. All included births were attended by midwives employed by the National Health Service (NHS) and registered with the Nursing Midwifery Council. Although having varying experience of waterbirth, all midwives are required to comply with national practice standards. Water immersion during labour or birth was recorded within mandatory record keeping by midwives and included immersion in a domestic bath or specialist birthing pool. Births in obstetric units, at home and in midwifery-led units were included. Births at which a midwife was not in attendance, either because the women chose to give birth without professional assistance, or because birth occurred at home or elsewhere before professional assistance arrived or could be reached, were excluded.

2.2 | Outcomes

The maternal primary outcome was OASI, and the neonatal primary outcome was a composite of perinatal mortality and specific neonatal morbidities: stillbirth with fetal death after the start of care in labour, neonatal death before discharge home, neonatal unit admission with respiratory support, or administration of intravenous antibiotics commenced within 48 hours of birth. The neonatal composite measure was designed to capture adverse outcomes previously reported as being associated with being born into water: birth asphyxia, water inhalation or sepsis.[12–15] Secondary outcomes included maternal and neonatal morbidities and outcomes associated with birth, including third-stage management, postpartum haemorrhage and treatment (Table S2a,b).[16]

2.3 | Data collection

Data were collected in local electronic maternity and neonatal information systems at participating sites. Demographic characteristics, and the labour and birth details, including use of water immersion and perineal trauma, required to inform the maternal primary outcome were existing fields

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within the maternity information system at all sites. Some fields that were required to report components of the neonatal primary outcome, or required to meet other study objectives, were not collected within existing systems. Therefore, 12 additional fields were added to the maternity information system at each study site, and these collected data prospectively from the date of the individual site opening (Table S3). One of these additional fields identified women who had opted out of the study, ensuring that their record was not included in data transfer. Data collection terminated early at sites if they discontinued use of the partnered maternity information system. For each birth, a single pseudonymised record combining individual-level maternity and neonatal unit data was created. Details of these procedures are fully described elsewhere.[16]

Analysis of the maternal primary outcome included births between 1 January 2015 and 30 June 2022, and where data were available, maternal and neonatal secondary outcomes also included births throughout this period. Data relating to all babies born at study sites throughout this period who were admitted to a neonatal unit following maternal water immersion during labour, were obtained from the National Neonatal Research Database.[17] To provide denominator data and inform comparative analysis, data relating to all births occurring during this period were extracted from sites.

Analysis of the neonatal primary outcome, and some maternal and neonatal secondary outcomes, was limited to births between the date that individual sites opened between January 2019 and April 2021, and 30 June 2022.

Analysis of maternal and neonatal primary outcomes was limited to women without antenatal or intrapartum factors or interventions indicating that birth in an obstetric unit should be recommended,[2] and without obstetric or anaesthetic input into care before birth. This included women without underlying medical or obstetric complications, in spontaneous labour, between 37^{+0} and 41^{+6} weeks of gestation, without oxytocin augmentation during labour or anaesthetic administered analgesics, with normal maternal and fetal observations throughout labour, and who gave birth spontaneously. Comparative characteristics of women who used, and those who did not use, water immersion during labour, will be reported separately, as will outcomes for women who used water immersion with antenatal risk factors[2]; and outcomes among women without risk factors at pool entry who received obstetric or anaesthetic interventions before birth.

2.4 | Statistical analysis

A sample size of 15 000 nulliparous and 15 000 parous women (7500 each of waterbirths and births out of water) was required in the primary maternal analysis to obtain 90% power, and a one-sided 95% CI around a treatment difference of zero. Sample size calculations were performed a priori and incorporated into the study protocol at design stage. The margins of difference included in the sample size calculations were those considered by the co-investigators and Patient and Public Involvement representatives to represent margins of clinical significance. A non-inferiority margin of ≤1% and ≤0.6% absolute difference was taken as clinically non-significant among nulliparous and parous women, respectively. A sample size of 16 200 infants (8100 each of waterbirths and births out of water) was required to have 90% power, and a one-sided 95% CI around a treatment difference of zero. A non-inferiority margin of 1.0% or less was taken as clinically non-significant. Sample size calculations are provided in the study protocol.[16]

For the primary outcomes, mixed-effects two-level logistic regression models were run and odds ratios (OR) were presented alongside a one-sided 95% CI (−∞ to upper limit), where the upper limit was compared with the predefined non-inferiority margins.[18] Non-inferiority would be concluded if the upper limit of the 95% CI for the difference in the proportion of OASI between the groups was less than 1.0% (OR ≤1.23) in nulliparous women and less than 0.6% (OR ≤1.38) in parous women. The data were then combined to assess the effects averaged across both strata. Non-inferiority would be concluded if the upper limit of the 95% CI for the difference in the infant outcome between the groups was less than 1.0% (OR ≤1.21).

The models allowed for clustering of outcomes within NHS site (as a random effect) and adjusted for (1) maternal age; (2) ethnic group (following Office for National Statistics categories[19]: https://www.ethnicity-facts-figures.service.gov.uk/style-guide/ethnic-groups White; Asian or Asian British; Black, Black British Caribbean or African; Mixed of multiple ethnic groups; Other ethnic group); (3) deprivation quintile (based on maternal postcode linked to the UK Townsend Score); (4) parity (nulliparous, no previous live births or stillbirths after 24^{+0} weeks gestation/multiparous), (5) gestational age; (6) body mass index; (7) birthweight; (8) season (Jan–Mar, Apr–June, Jul–Sept, Oct–Dec); (9) year of birth and (10) the presence/absence of complications apparent only once spontaneous vaginal birth was imminent. These covariates were selected given their associations with the maternal and infant primary outcomes.[20,21] Year and season of birth were included because midwifery practices may have changed over time as a result of changing guidelines (e.g. OASI Care Bundle).[22] If non-inferiority was established, then a superiority analysis was conducted as a secondary analysis of the primary outcomes, using logistic regression and presented as adjusted odds ratios, alongside a two-sided 95% CI. Planned (and powered, for maternal outcomes only) subgroup analyses of parity for both primary outcomes were conducted by inclusion of an interaction term (exposure × parity).

Sensitivity analyses were run. (1) The study reported outcomes reflecting clinical practice, including where a complication became apparent only once spontaneous vaginal birth was imminent, without obstetric intervention; we also reported outcomes among births without any such complications (and not adjusted for). (2) Inverse probability weighting was used to adjust for known and measured confounders

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as in the main analysis, reweighted on the propensity score. (3) Multiple imputation with chained equations was used to impute values for the missing data under the missing at random assumption, with parameter estimates and their standard errors combined using Rubin's rules.

We imputed missing covariate data using multiple imputation to generate ten data sets in line with guidance suggesting that the number of imputations should at least be equal to the proportion of missing data.[23] The imputation model included all covariates, and the outcome variable. (4) Instrumental variable analysis was run using the *ivregress 2sls* command in Stata, which tests both required assumptions (instrumental variable associated with exposure; instrumental variable not associated with outcome), with the proportion of women using water for labour or birth at each site, used as an instrumental variable. Instrumental variables can deal with the unobserved factors in selection bias and can add potential value to a study dealing with just observable factors.

Maternal and infant secondary outcomes underwent the same approach to analysis, depending on outcome (Table S2a,b). Among women who gave birth in water, the rates of haemorrhage were explored by whether, or not, the placenta was delivered in water. We examined the primary maternal and infant outcomes, and postpartum haemorrhage of ≥1000 mL, between these two groups.

A post-hoc analysis was added following analysis of neonatal secondary outcomes, that examined key infant outcomes (neonatal unit admission, neonatal unit admission with respiratory support, and administration of antibiotics within 48 hours of birth, receipt of therapeutic hypothermia, deaths) by the occurrence of umbilical cord snapping before it was clamped. Absolute risk differences were described alongside 95% CI. Similarly, key infant outcomes were reported between events of shoulder dystocia occurring in and out of water.

Data analysis was conducted using Stata version 17 (StataCorp LP, College Station, TX, USA). An independent steering committee oversaw the study.

2.5 | Patient and public involvement

The co-investigator group included two parent representatives, with lived experience of birth and waterbirth, and expertise in communicating with expectant parents. They were equal member of the study management group throughout the study.

3 | RESULTS

A total of 869 744 records were received from 26 UK NHS sites (Table S4) relating to births between January 2015 and June 2022, among which 783 792 (90.0%) women had no record of water immersion during labour or birth and 87 040 (10.0%) had used water immersion during labour (Figure 1). Women who used water immersion during labour with identified antenatal risk factors (13 811, 15.9%) or who developed identified intrapartum risk factors (12 827, 14.7%) will be reported separately. Across the 24 sites that provided data on women who opted out, 65 women (range 0–16 women per site) opted out of the study after site opening, with 11 (42%) sites recording no opt-outs during the data collection period.

A total of 60 402 (69.4%) birth records relating to women without antenatal or intrapartum risk factors who used water immersion during labour were eligible for inclusion in the main analysis. In all, 39 627 (65.6%) were waterbirths and

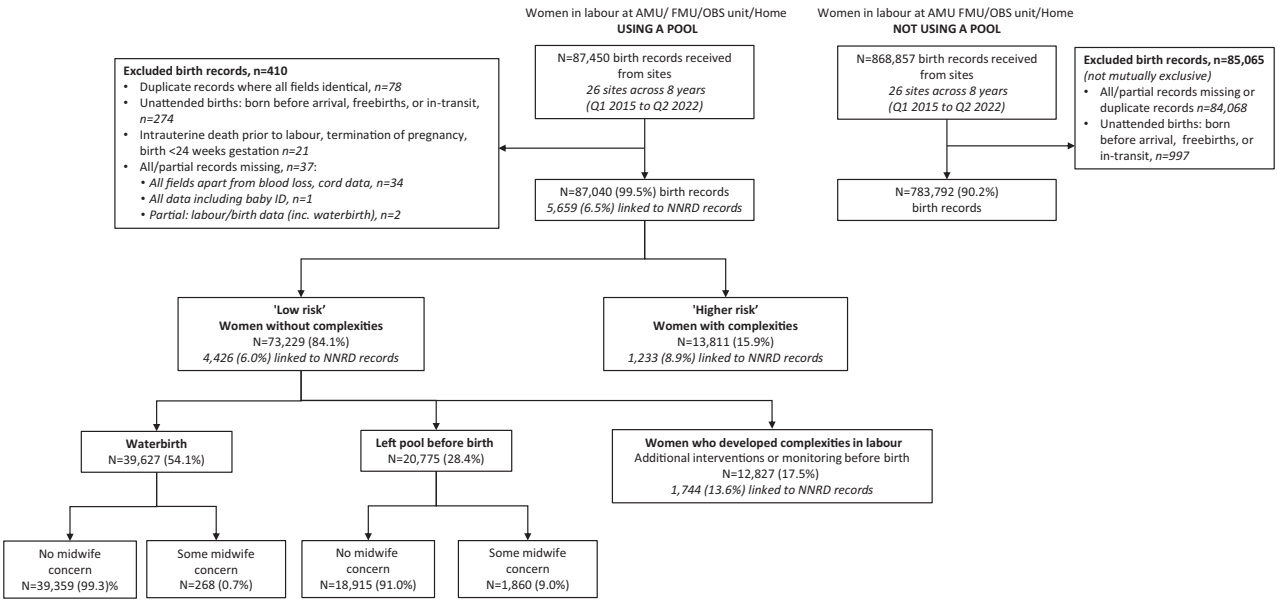


FIGURE 1 Flow chart of the study. AMU, Alongside Midwifery Unit; FMU, Freestanding Midwifery Unit; NNRD, National Neonatal Research Database; OBS, Obstetric unit; Q, Quarter.

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20 775 (34.4%) were births out of water. Of the 27 386 nulliparous women, 15 176 (55.4%) had a waterbirth compared with 24 451 (74.1%) of the 33 016 parous women (Table 1). Within each parity group, women who had a waterbirth were comparable on average to women who gave birth out of the water for maternal age (years), ethnic background, body mass index at booking, gestational age at birth and infant birthweight. Women residing in more affluent areas were more likely to have a waterbirth compared with more deprived women. Among the combined group of nulliparous and parous women, differences were observed in the proportion of births where complications became apparent only when spontaneous birth was imminent (0.7% waterbirths versus 9.0% births out of water).

The maternal primary outcome of OASI occurred in 730 (4.8%) of 15 176 nulliparous women who gave birth in water and 641 (5.3%) of 12 210 nulliparous women who left the pool before birth. The unadjusted odds ratio (uOR) was 0.91 (one-sided 95% CI −∞ to 0.99); the adjusted odds ratio (aOR) was 0.97 (one-sided 95% CI −∞ to 1.08) (Table 2). Similarly, fewer multiparous women in the waterbirth group had a recorded OASI than women who left the pool (269 of 24 451 women [1.1%] versus 144 of 8565 women [1.7%] respectively; uOR 0.65, one-sided 95% CI −∞ to 0.77, aOR 0.64, one-sided 95% CI −∞ to 0.78). The lower rate of OASI in water for multiparous women was sufficient that (as pre-specified) when tested in superiority analysis, it met thresholds of statistical significance (aOR 0.64, two-sided 95% CI 0.51 to 0.80). For nulliparous women, the lower rate of OASI did not meet the thresholds of statistical significance (aOR 0.97, two-sided 95% CI 0.86 to 1.11).

The composite adverse infant primary outcome occurred in 263 (2.7%) of 9868 infants in the waterbirth group and

TABLE 1 Maternal and infant demographics for waterbirths and births out of water, for all women and by parity.

	All women, *N* = 60 402		Nulliparous women (para 0), *N* = 27 386		Multiparous women (para 1–3[a]), *N* = 33 016	
	Waterbirth	Birth out of water	Waterbirth	Birth out of water	Waterbirth	Birth out of water
No. of birth records	39 627	20 775	15 176	12 210	24 451	8565
No. of birth records after site opening (% of all births)	10 760 (27.2%)	5463 (26.3%)	3878 (25.6%)	3075 (25.2%)	6882 (28.1%)	2388 (27.9%)
Maternal age (years), mean ± SD	29.9 ± 5.0	28.8 ± 5.2	28.2 ± 5.0	27.6 ± 5.1	31.0 ± 4.6	30.4 ± 4.9
Ethnicity						
White	32 420 (89.0%)	16 395 (87.9%)	12 183 (88.6%)	9572 (88.3%)	20 237 (89.2%)	6823 (87.5)
Asian or Asian British	1643 (4.5%)	1006 (5.4%)	590 (4.3%)	554 (5.1%)	1053 (4.6%)	452 (5.8%)
Black, Black British, Caribbean or African	686 (1.9%)	351 (1.9%)	268 (1.9%)	178 (1.6%)	418 (1.8%)	173 (2.2%)
Mixed or multiple ethnic groups	595 (1.6%)	280 (1.5%)	239 (1.7%)	166 (1.5%)	356 (1.6%)	114 (1.5%)
Other ethnic group	1096 (3.0%)	611 (3.3%)	467 (3.4%)	372 (3.4%)	629 (2.8%)	239 (3.1%)
Declined to answer/Not recorded	3187 (8.0%)	2132 (10.3%)	1429 (9.4%)	1368 (11.2%)	1759 (7.2%)	764 (8.9%)
Deprivation quintile by Townsend						
1—Most affluent	8605 (22.1%)	3887 (19.2%)	3062 (20.6%)	2230 (18.7%)	5543 (23.1%)	1657 (19.8%)
2	9435 (24.2%)	4579 (22.6%)	3539 (23.8%)	2705 (22.7%)	5896 (24.6%)	1874 (22.4%)
3	8488 (21.9%)	4435 (21.9%)	3339 (22.4%)	2703 (22.7%)	5149 (21.5%)	1732 (20.7%)
4	6905 (17.7%)	3913 (19.3%)	2758 (18.5%)	2377 (19.9%)	4147 (17.3%)	1536 (18.4%)
5—Most deprived	5475 (14.1%)	3472 (17.1%)	2202 (14.8%)	1911 (16.0%)	3273 (13.6%)	1561 (18.7%)
Not recorded	719 (1.8%)	489 (2.4%)	276 (1.8%)	284 (2.3%)	443 (1.8%)	205 (2.4%)
Parity—Nulliparous (para 0)	15 176 (38.3%)	12 210 (58.8%)	—	—	—	—
BMI at booking (kg/m^2), mean ± SD	24.3 ± 3.7	24.0 ± 3.8	24.0 ± 3.6	23.8 ± 3.7	24.4 ± 3.8	24.4 ± 3.9
Not recorded	4702 (11.9%)	1802 (8.7%)	1757 (11.6%)	1304 (10.7%)	2945 (12.0%)	768 (10.0%)
Gestation at birth (weeks), mean ± SD	40.1 ± 1.0	40.2 ± 1.0	40.0 ± 1.0	40.1 ± 1.0	40.2 ± 0.9	40.2 ± 0.9
Not recorded	135 (0.3%)	60 (0.3%)	45 (0.3%)	26 (0.2%)	90 (0.4%)	34 (0.4%)
Birthweight (grams), mean ± SD	3518 ± 409	3511 ± 421	3412 ± 386	3440 ± 399	3584 ± 409	3612 ± 431
Not recorded	71 (0.2%)	64 (0.3%)	30 (0.2%)	38 (0.3%)	41 (0.2%)	26 (0.3%)
Concern identified by midwife before birth	268 (0.7%)	1860 (9.0%)	112 (0.7%)	1204 (9.9%)	156 (0.6%)	656 (7.7%)

Abbreviations: BMI, body mass index; NICE, National Institute for Health and Care Excellence.

[a]Para 4$^+$ regarded as a risk factor by NICE.

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TABLE 2 Non-inferiority analyses of maternal and infant primary and key secondary outcomes.

	Waterbirth		Birth out of water		aOR[a] (1-sided 95% CI)
	N	*n* (%)	*N*	*n* (%)	
Primary outcomes					
Maternal: Obstetric anal sphincter injury (3rd/4th degree perineal injury) (W, MIS)					
Nulliparous women (para 0)	15 176	730 (4.8%)	12 210	641 (5.3%)	0.97 (−∞ to 1.08)
Multiparous women (para 1–3[b])	24 451	269 (1.1%)	8565	144 (1.7%)	0.64 (−∞ to 0.78)
All women	39 627	999 (2.5%)	20 775	785 (3.8%)	0.89 (−∞ to 0.98)
Infant: Adverse outcomes or treatment[c] (P, MIS/NNRD)	9868	263 (2.7%)	5078	224 (4.4%)	0.65 (−∞ to 0.79)
Separate components of the infant primary outcome					
Neonatal unit admission with respiratory support (P, NNRD)	10 760	96 (0.9%)	5463	109 (2.0%)	0.46 (−∞ to 0.62)
Neonatal unit admission with respiratory support (W, NNRD)	39 627	329 (0.8%)	20 775	320 (1.5%)	0.58 (−∞ to 0.68)
Intrapartum or neonatal death (W, MIS/NNRD)	39 627	7 (0.18 per 1000 births)	20 775	6 (0.29 per 1000 births)	0.22 (−∞ to 0.80)
Administration of intravenous antibiotics commenced within 48 h of birth[c] (P, MIS)	9868	181 (1.8%)	5078	149 (2.9%)	0.74 (−∞ to 0.94)
Administration of intravenous antibiotics commenced within 48 h of birth[c] (W, NNRD)	35 090	629 (1.8%)	18 693	535 (2.9%)	0.69 (−∞ to 0.77)
Key secondary outcomes: Maternal					
Shoulder dystocia recorded (W, MIS)	39 627	221 (0.6%)	20 775	651 (3.1%)	0.16 (−∞ to 0.18)
Postpartum haemorrhage[d]: total blood loss ≥1000 mL (W, MIS)	39 627	1165 (2.9%)	20 775	797 (3.8%)	0.90 (−∞ to 0.98)
Key secondary outcomes: Infant					
Snapped umbilical cord before clamping (P, MIS)	10 760	106 (1.0%)	5463	16 (0.3%)	3.89 (−∞ to 6.88)
Neonatal resuscitation at birth (W, NNRD)	39 627	1619 (4.1%)	20 775	1315 (6.3%)	0.61 (−∞ to 0.65)

Abbreviations: aOR, adjusted odds ratio; MIS, Maternity Information System; NNRD, National Neonatal Research Database; P, Prospective study population (after site opened to additional data collection); uOR, unadjusted odds ratio; W, Whole study population.

[a]Adjusted for year and quarter of birth, ethnic group, deprivation quintile, maternal age at birth, parity, gestational age, body mass index, birthweight (grams), concern identified by midwife before birth. Clustering of women within sites accounted for by fitting a two-level logistic regression model.

[b]Para 1–3 only—Para 4+ regarded as an antenatal risk factor, pool-users with recorded risk factors in their antenatal record or recorded by midwives at pool entry.

[c]Excludes data from four sites that did not record any postnatal outcome.

[d]Postpartum haemorrhage is determined from the estimated blood loss at/after delivery.

224 (4.4%) of 5078 infants born out of water (uOR 0.59, one-sided 95% CI −∞ to 0.69; aOR 0.65, one-sided 95% CI −∞ to 0.79) (Table 2). The lower rate of the infant primary outcome among babies born in water was sufficient that, when tested in superiority analysis, it met thresholds of statistical significance (aOR 0.65, two-sided 95% CI 0.52 to 0.82). The maternal and infant findings were consistent in the pre-specified sensitivity analyses and no differential effects due to parity were found in planned subgroup analyses (Table S5a,b). As the upper limits of the CIs for the difference in the primary outcomes between the groups were less than the pre-specified non-inferiority margins for both nulliparous and multiparous women of 1.0% (OR ≤1.23) and 0.6% (OR ≤1.38) respectively, and for the infant outcome of 1.0% (OR ≤1.21), non-inferiority was concluded (Figure 2).

Similar patterns were seen for each of the individual components within the composite infant primary outcome between groups (Table 2). Key secondary outcomes such as rates of perineal trauma postpartum haemorrhage (≥1000 mL) and neonatal resuscitation at birth, and outcomes following shoulder dystocia, also showed that waterbirth was non-inferior to birth out of water. Seven perinatal deaths occurred in the waterbirth group (0.18 per 1000 births) and six among births out of water (0.29 per 1000 births).

Maternal intrapartum secondary outcomes found no increase of shoulder dystocia, any perineal trauma, manual removal of the placenta or obstetric involvement in the woman's care following waterbirths compared with births out of water (Table S6). There was no suggestion of increased

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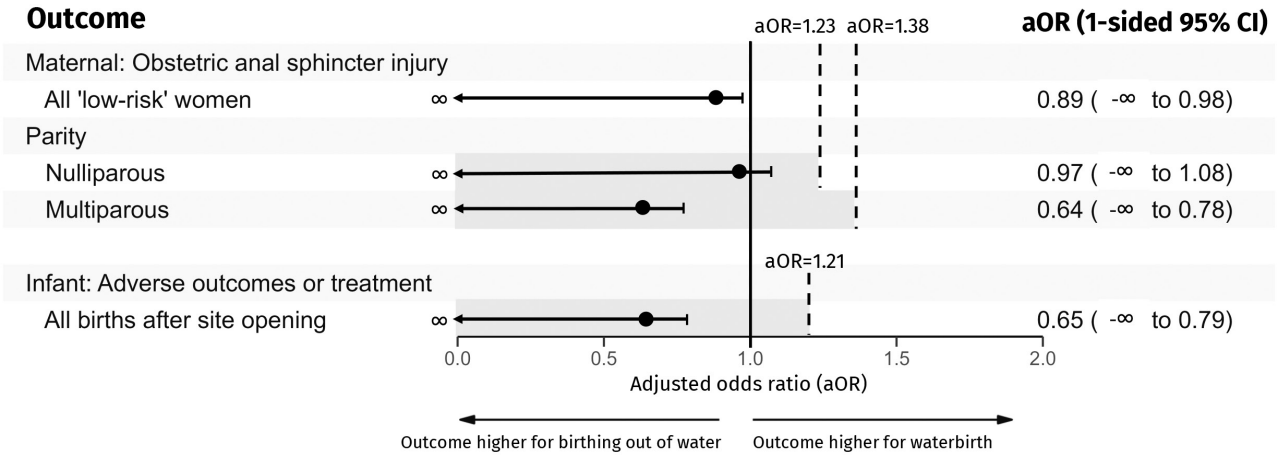


FIGURE 2 Forest plot of maternal and infant primary outcomes. Dashed lines represent the non-inferiority margin for each comparison and shaded areas represent the equivalence zone.

postnatal complications or lower breastfeeding initiation and continuation among births in water (Table S7).

There was no suggestion that patterns of serious genital trauma differed between women who gave birth in or out of water, either among nulliparous or parous women (Table S8).

Infant secondary outcomes suggested similar outcomes across groups, apart from the finding of a higher rate of the umbilical cord snapping before it was clamped among births in water compared with births out of water (1.0% versus 0.3%, uOR 3.39, one-sided 95% CI −∞ to 5.27; aOR 3.89, one-sided 95% CI −∞ to 6.88) (Table S9).

Among the 122 babies in both groups where their cord snapped before clamping, compared with babies where the cord was clamped before cutting, there were higher rates of neonatal unit admission, neonatal unit admission with respiratory support, and administration of antibiotics within 48 hours of birth (Table S10). No babies with a 'snapped cord' died, and none received therapeutic hypothermia for treatment of neonatal encephalopathy or a blood transfusion.

4 | DISCUSSION

4.1 | Main findings

The POOL Study is the largest UK-based study of water immersion during labour and has generated the high-quality evidence on maternal and neonatal outcomes associated with waterbirth requested by evidence-review and professional bodies over several years.[1–3,24]

The main study objective was to determine whether waterbirth, among women without antenatal or intrapartum risk who used water immersion during labour and were cared for by NHS midwives, increased risks for mothers or their babies compared with leaving the water before birth. The study found convincing evidence that rates of OASI among nulliparous and parous women were not higher during waterbirth, and rates of the neonatal primary outcome were no higher among babies born into water.

Higher rates of cord snapping before clamping occurred during waterbirth and although uncommon, were at rates above those previously reported.[8,9] There was no evidence of increase in rates of postpartum haemorrhage, or other measured maternal or neonatal morbidities when birth occurred in water.

4.2 | Strengths and limitations of the study

Due to the inability to conduct a randomised trial of sufficient size, a well-designed observational study was needed. Study strengths included sample size calculations based on reliable background rates of the primary outcomes[21] and predefined non-inferiority margins; methods and reporting followed guidelines for non-inferiority studies[25,26]; and the successful identification of women who did not receive obstetric or anaesthetic interventions before birth. The use of routine data facilitated generating a large data set with the required power to answer the study objective. On occasions, complications such as a fetal bradycardia developed close to birth but without the need for, or on occasions, the time to facilitate, obstetric involvement in the woman's care. It was important to reduce the potential influence of retrospective documentation of risk factors following adverse maternal or neonatal outcome. To reflect and mitigate this issue when a complication became apparent when spontaneous vaginal birth was imminent, but without recorded obstetric or anaesthetic involvement in the woman's care, women and their babies remained in the primary analysis. A separate important question was whether birth in water, when births are anticipated to be completely straightforward, impacts on maternal or neonatal outcomes. Sensitivity analysis, limited to births without documented complications after spontaneous vaginal birth was imminent, also found waterbirth to be associated with no increase in the primary maternal or neonatal outcomes. The absolute higher level of adverse neonatal outcomes among births out of water may reflect underreporting of identified complications, or other unidentified confounding factors.

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The POOL Study was the first to adapt electronic maternity information systems at individual NHS site level for the purpose of collecting research data. Using a combination of retrospective and prospectively collected data and adapting existing data systems created an efficient and novel data collection system.[27] Matching data held in electronic maternity records with that captured in the National Neonatal Research Database enabled the inclusion of outcomes relating to neonatal care. Twenty-six NHS study sites with wide geographical spread participated. Records were received from all participating sites relating to births that had occurred over a period of 8 years and the opt-out model resulted in the exclusion of few eligible births.

Limitations included the nature of routine clinical data. High levels of missing data were seen for some fields at some sites and some required data fields were not as specific or detailed as if designed specifically for research use. For example, four study sites did not enter data relating to postnatal care, and across all sites maternal assessment at hospital following discharge could not be distinguished from postnatal readmission. Infant readmissions to hospital could not be captured because babies requiring readmission were often admitted to paediatric units rather than maternity or neonatal units. Although the study was large, it remained underpowered to explore possible differences in rates of very rare outcomes, the potential remains that use of water immersion during labour was not captured in the electronic records of some women excluding them inappropriately, blood loss would be expected to be less accurately measured during waterbirths, and also unexplored confounders may have influenced study findings.

The generalisability of findings to other settings is not known but would be expected to be generalisable to settings with similar midwifery and maternity service provision. Care was provided by NHS-employed midwives. Although they have varying levels of experience of waterbirth, all are required to adhere to national[3] and locally approved guidance. There are clear criteria for pool use and pre-agreed referral pathways to obstetric and neonatal care and to anaesthetist-provided analgesia as required. Our findings may be less applicable to countries where care is provided differently, to births without trained midwifery attendance, or to births in the UK outside the NHS.

4.3 | Future research

Perineal trauma during vaginal birth was common. Further research is required to explore interventions to reduce rates of OASI and other perineal trauma during spontaneous vaginal births. Although around 10.0% of all women giving birth over the study period used water immersion, research into women's experiences of use of water during labour and birth remain relatively poorly explored.[28] The influence of water immersion during labour and birth on short and longer term psychological maternal outcomes warrants further investigation. Many practices during waterbirth, such as avoidance of tactile stimulation of the fetus during birth, estimation of blood loss, management of shoulder dystocia and care of the babies following snapping of the umbilical cord, lack high-quality evidence. Further research is required into these aspects of care.

5 | CONCLUSION

The use of water immersion during labour is valued by women as it provides a comfortable environment and personal space[28] in addition to analgesia.[29] The finding that risks to mothers and their babies are not increased among births in water concur with other smaller studies,[30] studies reporting outcomes of out of hospital births in the USA,[8,31] and those with different comparative groups.[6,10,32]

The qualitative component of The POOL Study identified professional reticence to offering waterbirth, particularly in obstetric units,[33] and practical and cultural barriers to women accessing water immersion during labour.[34] Study findings provide reassurance that birth in water, in the context of UK midwifery practice, is not associated with increased risks for mothers or their babies. Women considering or using water immersion during an uncomplicated labour should be informed that remaining in the water to give birth is not associated with increased risk to themselves or their baby, and they should be supported to make evidence-based individualised decisions on their care.

AUTHOR CONTRIBUTIONS

PB, RC-J, SC, BH, MJ, FL-W, CG, LM, SP, RP, MR and JS developed the study protocol. RM led study management. CB and RC-J managed and had access to the data. RC-J analysed the data. All authors interpreted the data. RC-J and JS drafted the manuscript. All authors edited the manuscript and accept responsibility for submitting the article for publication. The corresponding author attests that all listed authors meet the authorship criteria and that no others meeting the criteria have been omitted.

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CONFLICT OF INTEREST STATEMENT

NIHR provided funding to the employing institutions of JS, CB, PB, RC-J, SC, JC, BH, FL-W, SM, SP and MR to support the undertaking of the submitted work; CG received salary support from the Medical Research Council paid to his institution through a Personal Fellowship (Clinician Scientist and Transition Support). No other conflicts declared.

DATA AVAILABILITY STATEMENT

Applicants interested in requesting data for non-commercial purposes should apply via the data application form available on the Centre for Trials Research website (https://www.cardiff.ac.uk/centre-for-trials-research/collaborate-with-us/data-requests). Following an internal and peer review of the application and subject to approval, data may be released under a data transfer agreement. In the first instance, enquiries about access to the data should be addressed to Professor Julia Sanders, School of Healthcare Sciences, Cardiff University.

ETHICS APPROVAL

Research Ethics Committee (REC) approval was granted by the REC for Wales (18/WA/0291), and the transfer and use of identifiable data were approved by the Health Research Authority Confidentiality Advisory Group (18/CAG/0153). No consent was required from participants, but women in the prospective cohort could request for their data, and data relating to their baby, not to be included.

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SUPPORTING INFORMATION

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

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