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Is a randomized controlled trial of waterbirth possible? An Australian feasibility study

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Abstract

Background: The safety of waterbirth is contested because of the lack of evidence from randomized trials and conflicting results. This research assessed the feasibility of a prospective study of waterbirth (trial or cohort).

Methods: We conducted a prospective cohort study at an Australian maternity hospital. Eligible women with uncomplicated pregnancies at 36 weeks of gestation were recruited and surveyed about their willingness for randomization. The primary midwife assessed waterbirth eligibility and intention on admission in labor, and onset of second stage. Primary outcomes measured feasibility. Intention-to-treat analysis, and per-protocol analysis, compared clinical outcomes of women and their babies who intended waterbirth and nonwaterbirth at onset of second stage.

Results: 1260 participants were recruited; 15% (n = 188) agreed to randomization in a future trial. 550 women were analyzed by intention-to-treat analysis: 351 (waterbirth) and 199 (nonwaterbirth). In per-protocol analysis, 14% (n = 48) were excluded. Women in the waterbirth group were less likely to have amniotomy and more likely to have water immersion and physiological third stage. There were no differences in other measures of maternal morbidity. There were no significant differences between groups for serious neonatal morbidity; four cord avulsions occurred in the waterbirth group with none in the landbirth group. An RCT would need approximately 6000 women to be approached at onset of second stage.

Conclusions: A randomized trial of waterbirth compared with nonwaterbirth, powered to detect a difference in serious neonatal morbidity, is unlikely to be feasible. A powered prospective study with intention-to-treat analysis at onset of second stage is feasible.

KEYWORDS

childbirth, cohort study, feasibility, midwifery, waterbirth

1 | INTRODUCTION

Access to waterbirth (where a baby is born in water) is increasingly sought in many countries.[1-6] Birthing in water enhances women's sense of autonomy and control during childbirth;[7] women have measurably better childbirth experiences, compared with uncomplicated nonwaterbirth,[8,9] including lower pain scores.[10] Despite its popularity, waterbirth is largely unavailable in obstetric-led settings. Even when waterbirth is ostensibly readily available, for example 95% of maternity services in the United Kingdom,[4] access is affected by medically led environments that restrict pool use.[11] In Australia and the United Kingdom, waterbirth is recognized as an option for healthy women with uncomplicated pregnancies.[12-14] However, obstetric and pediatric colleges in the United States are opposed to waterbirth;[15,16] whereas in Canada, they cite a lack of adequate studies to determine safety.[17] Neonatal concerns include fetal temperature rises,[18,19] respiratory distress or water aspiration,[20,21] infection,[22,23] and "snapped" umbilical cords.[24,25] The problem, for both women and clinicians, is the limited high-quality evidence to demonstrate that waterbirth is either harmful or safe. Many published studies lack statistical power to reliably conclude about waterbirth safety or measure potentially rare complications.

A 2018 systematic review,[26] which offers highest level evidence, reported no adverse effects from water immersion in labor or birth to the fetus/newborn or woman. However, the meta-analysis of second-stage trials used data from 120 participants to report most outcomes.[26] The robustness offered by systematic review of randomized trials is undermined if the meta-analysis lacks the statistical power required to draw useful conclusions. A 2018, meta-analysis of 39 studies (12 592 waterbirths of 28 529 total births) examined neonatal outcomes. This study reported no evidence of neonatal harm and recommended future research of waterbirth was unlikely to change this result.[27] However, these conclusions were drawn from analysis of 39 studies, with a scant number of RCTs (n = 5), common use of retrospective study design (n = 22), and many studies that had small sample sizes <200 (n = 15).[27]

Two large prospective cohort studies of waterbirth, compared with landbirth, have been conducted in the past 20 years. A 2004 study compared outcomes for women according to actual place of birth: landbirth (n = 5901) or waterbirth (n = 3617); it concluded waterbirth was low risk.[28] A 2021 study compared outcomes for women in three groups (intended—actual place of birth): (1) land-land (n = 458), (2) water-water (n = 889), and (3) water-land (n = 730).[10] This study concluded there were similar rates of admission to neonatal intensive care unit (NICU) for all three groups.[10] Both studies used different statistical approaches to manage how to analyze women who "get out of the bath." The first approach (treatment-received analysis) analyzes women who get out of the bath in the landbirth group, which potentially biases that group toward worse outcomes (ie, women may get out because of a clinical indication).[29] The second approach (per-protocol analysis) treats women who get out of the bath as a separate group (or removes them altogether) to minimize confounding on outcomes in the landbirth group.[29]

Most studies that aim to determine clinical outcomes associated with waterbirth, compared with landbirth, use a retrospective cohort design.[5,30-37] According to the hierarchy of evidence, this is considered a weaker design, which is further undermined when studies are underpowered. For example, a recently published United States retrospective cohort study included 58 waterbirths compared with 172 nonwaterbirths,[38] a sample size too small to make meaningful conclusions. The strongest retrospective design to date is a 2021 propensity score matching study, which included 17 530 women having waterbirth, compared with the same number of women having landbirth, matched on >80 potentially confounding variables.[31] The study reported two risks associated with waterbirth: a higher likelihood of uterine infection (not requiring hospitalization), and cord avulsion, whereas other outcomes were improved or not different.

Several observational studies have shown that women who use a birthing pool for labor and/or birth are more likely to have a normal vaginal birth and are less likely to require labor augmentation, have an episiotomy, or receive epidural analgesia.[28,32,37,39-42] An increase in perineal trauma has been reported in waterbirth;[32,43] however, other research has found no increase in adverse events for women, including perineal trauma.[31,44-47] These mixed results, alongside concerns about potential harm to mothers and babies, selection bias in small and/or nonrandomized studies, and a lack of blinding, have resulted in ongoing recommendations to conduct robust prospective studies (trial or cohort).[16,26] As recently as April 2021, the American College of Obstetricians and Gynecologists advised women against waterbirth until further well-designed prospective studies were conducted.[16]

This study aimed to determine the feasibility of conducting a statistically powered noninferiority (NI) randomized controlled trial (RCT) or prospective cohort study. The primary hypothesis to be tested in a NI RCT would be that waterbirth is no worse than nonwaterbirth. The objectives of this study were to test recruitment parameters, data collection tools, suitability of outcome measures, and the acceptability of randomization.

2 | METHODS

2.1 | Setting

The study was conducted in a tertiary maternity facility in Australia, which supports more than 10 000 births per annum. Before this study, waterbirth was not available. The birth suite had 15 individual birth rooms; 9 rooms had a plumbed domestic bath (unsuitable for waterbirth), and 2 rooms had large circular plumbed birth pools purchased for this study (allocated to participants in the study planning waterbirth). There was one portable inflatable birth pool available for participant use if required. Waterbirth was only accessible to participants in the study.

2.2 | Participants

The key inclusion criteria were as follows: >15 years, did not require interpreter or legal guardian for consent, <100 kg, vertex, low obstetric risk (defined as suitable for intermittent auscultation in labor), singleton viable pregnancy, spontaneous labor at term with effective contractions not requiring oxytocic augmentation (determined by clinician), intact membranes, clear liquor or ruptured membranes with adequate intravenous antibiotic cover (as defined by clinical policy), vaginal bleeding of no more than a show, and normal maternal and fetal observations. The key exclusion criteria were: blood-borne infection (eg, hepatitis B, hepatitis C, and HIV), major congenital anomalies, <37 weeks of gestation or >42 weeks of gestation, induction, augmentation, or planned cesarean, any suspected or proven active infectious illness (eg, genital herpes), and narcotic or epidural analgesia.

2.3 | Recruitment

Participants were recruited between October 2014 and September 2017 in the antenatal clinic, midwifery group practice (midwifery continuity of caregiver program), pregnancy assessment unit, and birth suite. Recruitment was primarily conducted by clinicians as resources limited the availability of a 24/7 research assistant. Women planning waterbirth or nonwaterbirth, with or without water immersion in labor, were screened as potential participants using eligibility criteria. Eligibility was reassessed on admission to hospital for birth, throughout the first stage of labor and at the onset of the second stage. Participants who developed conditions that rendered them ineligible before onset of second-stage labor were excluded from analysis.

2.4 | Intended waterbirth group

We developed a multipronged educational strategy to ensure clinicians had the requisite knowledge and skills to offer waterbirth competently and in accordance with the clinical procedure. The clinical procedure was informed by the Australian and United Kingdom professional position statements,[12-14] and clinical guidelines;[48-52] and then cross-referenced with related hospital policies for intrapartum care. We were granted permission to adapt an Australian online learning package (Government of Western Australia)[53] to fit the setting and align with relevant clinical policies; the package included an online quiz. Face-to-face education was conducted through a 1-day multidisciplinary workshop, one-to-one assessment of waterbirth competency through simulated practice, and regular emergency drills in birth suite.

Women who intended waterbirth on admission to birth suite were allocated to a room with waterbirth facilities (large bath without jets) and had one-to-one midwifery care. All women had at least one waterbirth-accredited clinician (midwives and/or obstetricians) in the room during birth itself, along with a water immersion-accredited midwife. Women could access deep warm water immersion in labor, and in the absence of an indication or desire to exit the pool, the woman would proceed to give birth in water. Birth was conducted using an evidence-informed clinical procedure for waterbirth including the following: (a) monitoring water temperature every 15 minutes during second stage (37.0-37.5 degrees); (b) observing progress using a torch and mirror if needed; (c) keeping hands-off until baby fully born in water; (d) bringing baby to surface immediately after birth; (e) checking cord is intact; and (f) maintaining skin-to-skin contact. If the woman planned an active management of third stage, she exited the pool before administration of the oxytocic. If the woman chose physiological third stage, she was able to stay in the pool and birth the placenta in water.

2.5 | Intended nonwaterbirth group

Women who intended nonwaterbirth on admission to birth suite were allocated a room with access to a domestic bath for warm water immersion; and received one-to-one midwifery care. Women who used the bath during first-stage labor were asked to exit the bath at the onset of second-stage labor and give birth in a position of their choice. Third stage of labor, active or physiological, was also conducted out of the bath.

2.6 | Feasibility outcomes

The primary feasibility outcomes were recruitment parameters (potentially eligible; recruited) and participant flow, including the number of women who were eligible: on admission to birth suite; at onset of second stage; and the number of women who intended to waterbirth at both time points—the number of women who had a waterbirth and the number who were agreeable to being randomized in a future trial.

2.7 | Primary and secondary outcomes for the main study

We defined the primary outcome for the main study, as a serious neonatal adverse event comprising one or more of the following secondary outcomes: perinatal death (includes stillbirth/fetal death in labor after study entry and death of a live born infant before discharge from hospital); complex resuscitation (includes intubation for ventilation, cardiac massage, and/or administration of resuscitation drugs); hypoxic-ischemic encephalopathy (HIE) 2 or 3; seizures under 48 hours; Apgar score <4 at 5 minutes; admission to NICU >4 days (96 hours); and proven systemic infection in first 48 hours of life (treated with antibiotics). All outcomes were defined a priori and are listed in the Australian and New Zealand Clinical Trials Register (ACTRN12616000973415).

2.8 | Data sources and measurement

Along with patient details, a paper recruitment form was used to collect each participant's intention for birth (water immersion, waterbirth, neither) and whether they would agree to participate in a future RCT of waterbirth (yes, no, undecided) at time of recruitment (late pregnancy or admission in labor). This information was input into a purpose-built database. An additional electronic data item was created in the hospital's perinatal database for the midwife to enter the woman's intention for birth at onset of second stage. Routinely collected data entered into the hospital's perinatal database and administration systems were extracted. Where required, health records were audited to validate data.

2.9 | Statistical methods

Analysis of feasibility outcomes was conducted using simple descriptive statistics and multivariate analysis. Primary analysis was intention-to-treat (ITT) at onset of second stage. Variables that were statistically significant in the univariate analyses between intention to waterbirth versus nonwaterbirth on second stage of labor were adjusted in the multivariable model for the primary and secondary clinical outcomes. A post hoc per-protocol analysis was conducted by excluding those women who did not birth in water. Relative risk ratio and 95% confidence interval for binary outcomes and relative increment and 95% confidence interval for continuous outcomes were reported. A two-tailed $P < .05$ was statistically significant. Statistical analyses were completed using Stata 14.1.

2.10 | Ethical considerations

The study was conducted after approval from the hospital's Human Research Ethics Committee. Women who met the eligibility criteria and were keen to participate in the study provided written informed consent and their personal details to enable follow-up by the research team. An independent data and safety monitoring committee (DSMC) was established to examine adverse and serious adverse events and to assess causality.

3 | RESULTS

In total, 11 804 of 31 485 women were potentially eligible during the recruitment period. Of the potentially eligible women, 10.7% were recruited. Fifteen percent of participants (n = 188) who were recruited during pregnancy indicated they were agreeable to randomization in a future waterbirth RCT. The proportion of participants eligible on admission to birth suite and at onset of second stage are presented in Figure 1, alongside the primary indication for exclusion at each stage.

The proportion of participants who gave birth in water were as follows: 24% of participants recruited during pregnancy (303/1260); 35% of participants who were eligible on admission in labor to birth suite (303/876); and 55% of participants who were eligible at onset of second-stage labor (303/550) and 86% of those intending to have a waterbirth at onset of second stage (303/351). Crossover was unidirectional with 14% (n = 48) of women who intended a waterbirth having a landbirth. Participant characteristics are summarised in Table 1.

Sample size modeling for a future RCT or prospective cohort study was undertaken (Table 2). The required sample size for a noninferiority (NI) trial depends on the baseline rate for the primary outcome, minimal acceptable NI margin, and the time in pregnancy that recruitment occurs. We used a 1.0% baseline rate for the neonatal

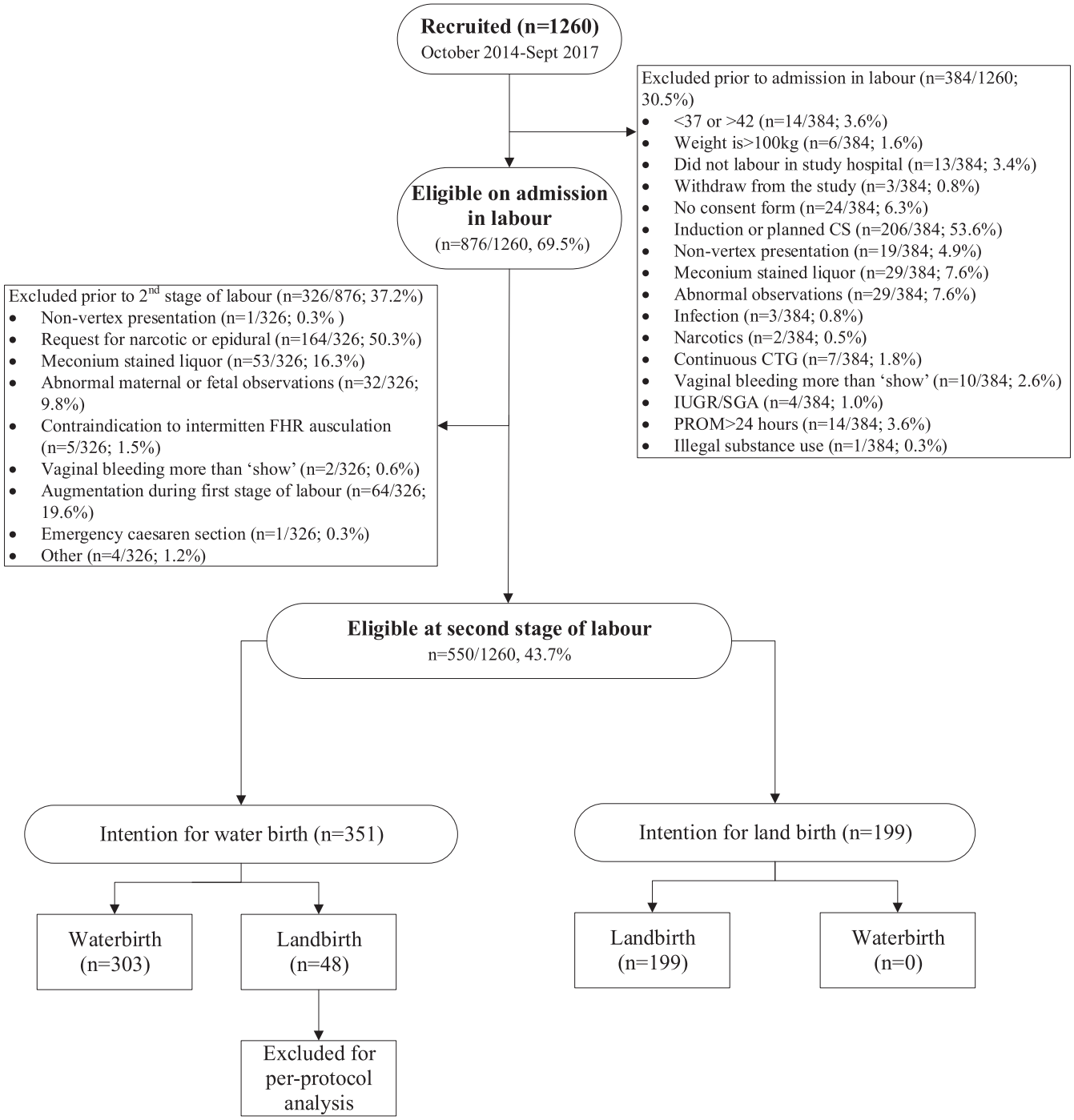

FIGURE 1 Participant flow

morbidity composite (based on our study findings) and a 2% NI margin (based on the margin used in the planned vaginal birth or elective repeat cesarean study).[54] To detect this clinically significant difference (80% power, alpha 0.025%), we estimated the number needed to be recruited at three different time points: antenatally, admission to birth suite (onset of labor), and at onset of second stage (or late first stage) to conduct either a prospective cohort study or a RCT (Table 2). We have provided the numbers needed for more conservative minimal acceptable NI margins increasing by 0.5% for each scenario to: 1.5%, 2.0%, 2.5%, or 3.0% (Table 2).

Some components of the neonatal composite were unable to be accurately obtained (ie, proven infection); or required coding based on review of hand-written medical records (ie, hypoxic-ischemic encephalopathy, seizures <48 hours). This means for a future study of waterbirth in this setting; these outcome measures cannot be efficiently and reliably captured and should be removed or would need study specific data collection. Cord blood samples

TABLE 1 Demographic and pregnancy characteristics by intention to waterbirth for 550 women who were eligible at onset of second stage of labor

	Waterbirth (n = 351)		Nonwaterbirth (n = 199)		
	Median	**IQR**	**Median**	**IQR**	***P*-value**
Age	31	28-34	30	27-33	**.035**
Body mass index at booking (kg/m^2)	21.9	20.2-24.7	21.9	20.3-24.2	.533
	N	**%**	**N**	**%**	***P*-value**
Education level					
Grade 10 and lower	15	4.3	8	4.1	.073
Grade 11-12	66	19.0	54	27.4	
Tertiary	267	76.7	135	68.5	
Ethnicity					
Indigenous Australian	16	4.6	8	4.0	.086
Caucasian	287	81.8	147	73.9	
Asian	19	5.4	16	8.0	
Other	29	8.3	28	14.1	
Public funding status	331	94.3	195	98.0	**.042**
Nulliparity	149	42.5	80	40.2	.607
Smoker at booking	9	2.6	12	6.0	**.042**
EPDS >12 at booking	12	4.0	6	3.3	.672
Heart disease	6	1.7	4	2.0	.753
Gestational diabetes	4	1.1	3	1.5	.708
Hemoglobin <110 g/L at booking	4	1.2	3	1.6	.711
Intending to breastfeed at booking	332	97.1	184	98.9	.655

Note: Nonparametric test for continuous variables: the Mann-Whitney test. The Fisher exact two-tailed *P*-value was calculated when expected value is <5 in any cell.

Abbreviations: EPDS, Edinburgh Postnatal Depression Score; IQR, interquartile range.

Bold values indicate statistical significance (<0.05).

TABLE 2 Sample size calculation with a noninferiority RCT and prospective cohort design

Number of women having a waterbirth	Number of women having a birth out of water	Baseline neonatal composite in control	Minimal acceptable noninferiority margin	Proportion of neonatal composite in waterbirth group	Total number to be approached if recruiting in pregnancy	Total number to be approached if recruiting at admission in labor	Total number to be approached if recruiting at onset of second stage
Randomized controlled trial design[a]							
6217	6217	1.0%	0.5%	1.5%	460 519	169 170	96 388
1555	1555	1.0%	1.0%	2.0%	115 185	42 313	24 109
691	691	1.0%	1.5%	2.5%	51 185	18 803	10 713
389	389	1.0%	2.0%	3.0%	28 815	10 585	6031
Prospective cohort design[b]							
6217	6217	1.0%	0.5%	1.5%	80 323	29 506	16 812
1555	1555	1.0%	1.0%	2.0%	20 090	7380	4205
691	691	1.0%	1.5%	2.5%	8928	3280	1869
389	389	1.0%	2.0%	3.0%	5026	1846	1052

[a]Based on our study results, the RCT design calculation factors that 15% of women approached will agree to randomization and therefore be recruited.

[b]The prospective cohort design factors that 86% of women would agree to be recruited, based on results reported in Lewis et al The perceptions and experiences of women who achieved and did not achieve a waterbirth—*BMC Pregnancy Childbirth* 2018;18(23). Both calculations include a 31% dropout rate between recruitment in pregnancy and being admitted to birth suite in labor; a 37% dropout rate between being admitted to birth suite in labor and onset of second stage; and a 14% crossover rate between second stage of labor and birth, based on our study results.

were not taken and would not be recommended for the main study because of occupational safety concerns of attempting to take these when women and babies are in the bath. As results were only available for a small proportion of babies, it is not a reliable outcome measure for the main study.

Women in the intended waterbirth group had a lower chance of amniotomy, a higher chance of warm water immersion, and a higher chance of physiological third stage (Table 3). Other maternal outcomes including mode of birth, perineal status, and postpartum hemorrhage were similar between the comparison groups for ITT analysis (Table 3) and per-protocol analysis (Table S1). For babies in the intended waterbirth group, there was one significant difference; infants who were admitted to neonatal nursery had a shorter stay (Table 4). In the per-protocol analysis, there was no difference between groups on any measure (Table S2). There was no significant difference in other outcomes, including serious neonatal morbidity, when compared to babies in the

TABLE 3 Labor and birth outcomes for 550 women who were eligible at onset of second stage of labor

	Waterbirth (n = 351)		Nonwaterbirth (n = 199)		Adjusted risk ratio[a] (95% CI)	*P*-value
	N	%	N	%		
Amniotomy	36	10.3	47	23.6	**0.44 (0.30, 0.66)**	**<.001**
Oxytocic augmentation	3	0.9	3	1.5	0.52 (0.11, 2.57)	.427
Any water immersion	342	97.4	68	34.2	**2.91 (2.39, 3.53)**	**<.001**
Nitrous oxide gas	134	38.2	87	43.7	0.90 (0.73, 1.11)	.339
Nonpharmacological analgesia	328	93.4	182	91.5	1.02 (0.97, 1.08)	.403
Epidural	0	0.0	0	0.0	–	–
Meconium liquor at birth	16	4.6	6	3.0	1.54 (0.61, 3.91)	.360
Intrapartum abnormal heart rate	0	0.0	0	0.0	–	–
Mode of birth						
Instrumental vaginal birth	7	2.0	9	4.5	0.48 (0.18, 1.28)	.143
Maternal temperature in labor[b]	7	2.1	5	2.9	0.79 (0.25, 2.47)	.682
Maternal collapse	0	0.0	0	0.0	–	–
Maternal antibiotics in labor	16	4.6	12	6.0	0.87 (0.42, 1.79)	.697
Physiological third stage	156	44.4	41	20.6	**2.20 (1.63, 2.96)**	**<.001**
Postpartum hemorrhage (≥500 mL)	36	8.3	19	9.5	1.11 (0.65, 1.89)	.709
3rd/4th-degree perineal tear	15	4.3	5	2.5	1.78 (0.66, 4.82)	.255
Admission to intensive care unit	0	0.0	0	0.0	–	–
Maternal death	0	0.0	0	0.0	–	–
Postnatal readmission to hospital	9	2.6	6	3.0	0.84 (0.30, 2.32)	.734
	Median	**IQR**	**Median**	**IQR**	**Adjusted relative increase[a] (95% CI)**	***P*-value**
Duration of each stage labor						
First stage (min)	220	135-360	210	130-360	27.87 (−13.65, 69.39)	.188
Second stage (min)	18	7-44	15	6-44	0.26 (−6.62, 7.15)	.940
Third stage (min)	20	12-33	11	8-19	**7.21 (3.67, 10.75)**	**<.001**
Length of time in pool (min)	90	50-144	85	44-128	16.61 (−3.90, 37.12)	.112
Length of postnatal stay (d)	1	0-2	1	0-2	−0.04 (−0.24, 0.16)	.677

[a]Adjusted for maternal age, insurance, and smoking status at booking.

[b]≥37.5°C.

Bold values indicate statistical significance (<0.05).

TABLE 4 Neonatal outcomes by intention to waterbirth for 550 women who were eligible at onset of second stage of labor

	Waterbirth (n = 351)		Nonwaterbirth (n = 199)		Adjusted risk ratio[a]	
	N	%	N	%	(95% CI)	*P*-value
Serious neonatal morbidity[b]	3	0.9	2	1.0	1.02 (0.17, 6.18)	.986
Perinatal death	0	0	0	0	–	–
Complex resuscitation	2	0.6	2	1.0	0.71 (0.10, 5.14)	.734
Hypoxic-ischemic encephalopathy	1	0.3	1	0.5	0.51 (0.03, 8.22)	.638
Seizures under 48 h	0	0	0	0	–	–
Intensive care unit >96 h	2	0.6	2	1.0	1.54 (0.14, 17.53)	.727
Proven infection	0	0	0	0	–	–
Apgar <4 at 5 min	0	0.0	1	0.5	–	.362
Apgar <7 at 5 min	3	0.9	1	0.5	2.18 (0.22, 21.41)	.504
Positive pressure ventilation	3	0.9	3	1.5	0.71 (0.14, 3.54)	.673
Inspired oxygen >30%, CPAP, or invasive ventilation	5	1.4	2	1.0	3.21 (0.37, 27.83)	.288
Any separate nursery admission	10	2.8	2	1.0	3.01 (0.66, 13.71)	.153
Special care nursery admission	2	0.6	1	0.5	1.12 (0.10, 12.37)	.925
NICU admission	8	2.3	1	0.5	4.95 (0.62, 39.77)	.130
Snapped cord	4	1.1	0	0.0	–	–
Neonatal blood transfusion	0	0.0	0	0.0	–	–
Neonatal academia[c]	2	0.6	4	2.0	0.28 (0.05, 1.53)	.142
Neonatal temperature ≥37.5	10	2.8	5	2.5	1.15 (0.40, 3.32)	.797
Antibiotics administered	4	1.1	4	2.0	0.65 (0.16, 2.66)	.549
Skin-to-skin contact >60 min	276	78.6	155	77.9	0.99 (0.91, 1.09)	.892
Breastfeeding at birth	336	95.7	192	96.5	0.99 (0.95, 1.02)	.475
Timing of first breastfeed ≤60 min	286	85.4	158	81.9	1.03 (0.95, 1.12)	.415
Feeding directly at the breast only at hospital discharge	315	89.7	182	91.5	0.96 (0.91, 1.02)	.230
	Median	**IQR**	**Median**	**IQR**	**Adjusted relative increase[a] (95% CI)**	***P*-value**
Length of stay						
Neonatal nursery (h) for 12 babies admitted	19	13-30	132	112-152	**−100.16 (−199.90, −0.42)**	**.049**
Hospital (d)	1	0-2	1	0-2	−0.14 (−0.36, 0.16)	.454

[a]Adjusted for maternal age, insurance, and smoking status at booking.

[b]Serious neonatal morbidity composite (with individual components reported in shaded gray): perinatal death; complex resuscitation, which includes intubation for ventilation, cardiac massage and/or the administration of drugs of resuscitation (eg, adrenaline, sodium bicarbonate, fluids); hypoxic-ischemic encephalopathy (HIE) 2 or 3; seizures under 48 h; Apgar score <4 at 5 min; admission to NICU >4 days (96 h); proven systemic infection in first 48 h of life (treated with antibiotics).

[c]Arterial cord blood pH <7 and/or blood base excess <−10.0.

Bold values indicate statistical significance (<0.05).

intended nonwaterbirth group (Table 4). However, there were four snapped cords in the waterbirth group (1.1%) and none for women birthing out of water (Tables 4 and Table S2). No babies required a blood transfusion, although two babies with cord avulsion were admitted into the neonatal nursery for approximately 13 hours each.

4 | DISCUSSION

4.1 | Main findings

This research assessed the feasibility of undertaking a prospective study of waterbirth (NI RCT or cohort design) powered to detect a difference in serious neonatal

morbidity. A high proportion of potentially eligible women did not participate. This study had few research assistants to recruit women in the antenatal period, which meant recruitment largely relied on proactive women and clinicians. At the same time, there was a general lack of support from many private obstetricians. In the study setting, 40% of births were conducted with a private obstetrician, but only 5% of study participants were private patients. Although it was possible to recruit women during pregnancy, most became ineligible before admission to hospital for birth, commonly because of induction of labor or planned cesarean. Approximately 40% of women who were eligible on admission for birth became ineligible by onset of second stage, most commonly because of administration of narcotics or epidural analgesia. Conversely, women who were eligible and planning a waterbirth at onset of second stage were likely to proceed with birth in water (86%).

Based on a 2% NI margin, an RCT design would need to assess 28 815 women for eligibility during pregnancy compared with 6031 if randomizing close to second stage (Table 2). Based on the same NI margin, a cohort design would need to approach 5026 women during pregnancy compared with 1052 near to second stage. However, if a 1% NI margin was deemed a more acceptable parameter for safety, then there is a fourfold increase in the number of participants required for either design. For a future study, these findings suggest the most feasible way forward is a prospective study of waterbirth rather than an RCT.

Secondary outcomes showed minimal differences. Like other prospective studies of waterbirth compared with landbirth,[10,28] our study demonstrated maternal benefits associated with waterbirth without additional risks. The occurrence of cord avulsion in the waterbirth group (and not the landbirth group) was not measured or reported by previous prospective studies.[10,28] However, a 2012 study of water immersion in different settings reported that 90% of all umbilical cord snaps occurred during waterbirths.[46] Indeed, the finding is consistent with the largest study to date,[31] which reported a significant risk of cord avulsion (OR 1.57, 95% CI 1.37-1.82) associated with waterbirth compared with landbirth; none were associated with neonatal death. The composite outcome of serious neonatal morbidity, which we anticipated would be the primary outcome for the main study, was not different between the groups in either ITT or per-protocol analysis. Low Apgar score has since been demonstrated to be unreliable as a morbidity outcome.[55] Based on our modeling, we recommend using admission to neonatal nursery >48 hours as the primary outcome for future prospective studies on the safety of waterbirth as it effectively captures serious neonatal morbidity and reduces bias from unblinded clinicians.

4.2 | Strengths and limitations

Our study is third largest prospective cohort design that compares clinical outcomes for waterbirth, compared with landbirth, in the last 20 years. Significantly, it is the only prospective study of waterbirth to use ITT analysis (estimating what would occur to women planning waterbirth at second stage) and per-protocol analysis (estimating the effect of waterbirth itself). Our design reflects what is likely to happen in the real-world setting, where a proportion of women will exit the bath and excluding them from analysis is open to critique,[56] but including them is not a true reflection of safety for babies born underwater. Our outcomes were defined a priori; a future study would also be strengthened by prior publication of a statistical analysis plan.[57]

Although 14% of women who intended waterbirth at onset of second stage had an actual landbirth, this is reassuring rather than concerning. The clinicians used an evidence-informed clinical guideline for monitoring women and babies in labor, including when to advise exiting the bath. Therefore, exiting the pool in second-stage labor by choice or because of clinical indication is part of the waterbirth intervention. This type of design is commonly used in studies of planned home birth;[58,59] another complex intervention that resists randomization, and where "crossover" is key to safe delivery of the intervention. These studies use ITT analysis according to the woman's birthplace intention (home or hospital) and eligibility for home birth, determined at the onset of labor. Like our study, this minimizes differences and confounding variables so that similarly low-risk women are represented in both groups. Furthermore, like our study, "crossing over" into hospital birth (when a planned home birth results in transfer to hospital) is considered part of the safety of the home birth intervention; it is not a threat to treatment fidelity.

However, the study demonstrates significant feasibility issues with the conduct of not only a trial but also a prospective cohort study. The study was designed to assess feasibility and was not powered for safety, and there were several limitations. First, it was undertaken at one very large hospital in the state of Queensland where waterbirth was a new option for women and new practice for clinicians. Despite a substantial education and upskilling program, it is possible that clinicians who were recruiting women antenatally were inexperienced and potentially biased in how they communicated with potential participants, which may have affected recruitment rates. Furthermore, the number of waterbirths conducted and potentially the clinical outcomes associated with waterbirth (eg, cord snap) may not be representative of other hospitals in Australia or overseas where waterbirth is

routinely offered. At the same time, when an option is routinely available, women are much less likely to agree to randomization, which threatens feasibility of an RCT and favors a cohort design. Second, the study was largely unfunded, which meant recruitment relied on proactive clinicians and women seeking access to waterbirth through participation in the study. Therefore, the recruitment rate is likely much lower than what could be achieved in an adequately funded trial. Third, numbers were too small to determine uncommon but significant outcomes (eg, neonatal death), and may also have been affected by clinician bias because of the unblinded nature of the study. Fourth, objective measures of fetal well-being (ie, cord gases) were not used.

4.3 | Interpretation

The low proportion of participants who would agree to randomization is consistent with evidence that women are less inclined to agree to participate in randomization when they have a firm belief that the intervention is either superior or inferior.[60] Even if a large RCT was pursued, the women who agreed to be in the trial would not necessarily be representative of the women who seek and feel passionate about waterbirth as they would be more inclined to decline randomization in order to get their birth choice. Taken together, the findings indicate that although information about the study can be provided during pregnancy, participants are best recruited just before onset of second-stage labor. Despite concerns of vulnerability, pain, and opiate analgesia, evidence suggests women do have the capacity to give informed consent in the intrapartum period to take part in studies.[61] However, with an RCT design there is potential psychological distress caused by withholding randomization until second stage, when women who want waterbirth may be asked to exit the pool against their wishes. Furthermore, midwives may be reluctant to recruit women to a study that would require them to ask women immersing in first-stage labor to good effect, to leave the pool. This raises ethical concerns as to whether the risks participation for the woman outweigh the potential benefits for the research. Furthermore, women may decline to leave the pool, impacting treatment fidelity, and make interpretation of an RCT very difficult.[62]

The lack of acceptability and feasibility for an RCT may explain why, despite over 40 years of waterbirth being accessible in hospital settings, there has never been a trial of adequate size to conclusively determine safety. Therefore, three options remain. The first is to accept the best available evidence that waterbirth is unlikely to confer additional risk to women and babies who have skilled care practitioners, appropriate intrapartum monitoring, and rigorous criteria for entering and exiting the bath. However, the risk of cord avulsion may increase with waterbirth compared with landbirth, as was reported in this study and the 2021 propensity matching study.[31] The second would be to consider a meta-analysis using individual patient data of prospective studies only including RCTs, and advanced statistical methods to manage confounding.[63] This would enable both an intention-to-treat analysis and a treatment-received analysis; increases in statistical power; standardization of inclusion criteria, outcome measures, and time points; and exclusion of retrospective studies. The third option is to conduct an adequately powered prospective cohort study to detect significant differences in maternal and neonatal morbidity. Using observational data combined with advanced statistical analysis such as propensity score matching or inverse probability of treatment propensity score weighting approach would sufficiently control confounding, which provides consistent treatment effect estimates when RCTs are not possible.[64]

4.4 | Conclusions

An adequately powered randomized trial of waterbirth is unlikely to be feasible. We argue it is time to relinquish the holy grail of a large RCT to confirm or refute safety of waterbirth.[27] A prospective cohort design using intention-to-treat analysis at onset of second stage addresses many of the methodological criticisms of previous studies.

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ETHICAL APPROVAL STATEMENT

The study was conducted after approval from the Mater Misericordiae Limited Human Research Ethics Committee (#HREC/13/MHS/176).

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The

data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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