ORIGINAL ARTICLE

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

Jyai Allen BA, BMid, PhD[1] | Yu Gao MD, PhD, GCHEcon[2] |
Hannah Dahlen BN(Hons), MCommN, Grad Cert (pharm), PhD[3] |
Maree Reynolds MN[4] | Michael Beckmann MBBS, FRANZCOG, PhD[4] |
Catherine Cooper BA, Grad Cert Hlth Ldr[4] | Sue Kildea BHSc. (Hons), PhD, Grad Cert
(teaching and learning for higher education)[2] (ORCID)

[1]School of Nursing and Midwifery,
Griffith University, Meadowbrook,
Queensland, Australia

[2]Molly Wardaguga Research Centre,
College of Nursing and Midwifery,
Charles Darwin University, Brisbane,
Queensland, Australia

[3]School of Nursing and Midwifery,
Western Sydney University, Penrith,
New South Wales, Australia

[4]Mater Mothers' Hospitals, Raymond
Terrace, South Brisbane, Queensland,
Australia

**Correspondence**
Jyai Allen, School of Nursing and
Midwifery, Griffith University (Logan
Campus), University Drive, Building
L05, Meadowbrook, QLD 4131,
Australia.
Email: jyai.allen@griffith.edu.au

## 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
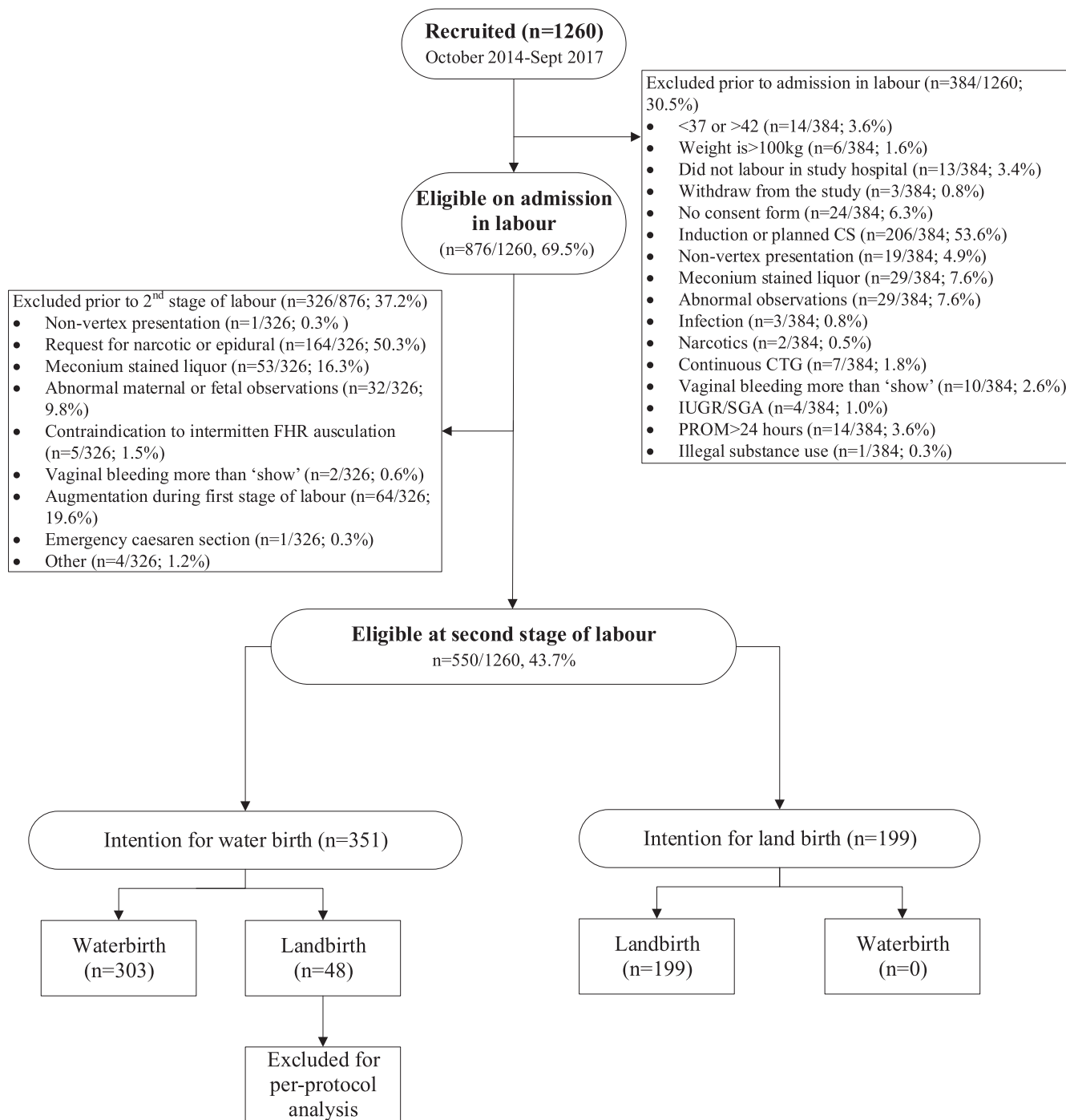
**FIGURE 1**  Participant flow

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 | | | | | .073 |
|   Grade 10 and lower | 15 | 4.3 | 8 | 4.1 | |
|   Grade 11-12 | 66 | 19.0 | 54 | 27.4 | |
|   Tertiary | 267 | 76.7 | 135 | 68.5 | |
| Ethnicity | | | | | .086 |
|   Indigenous Australian | 16 | 4.6 | 8 | 4.0 | |
|   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] | |
|---|---|---|---|---|---|---|
| | N | % | N | % | (95% CI) | P-value |
| 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] (95% CI) | P-value |
|---|---|---|---|---|---|---|
| | N | % | N | % | | |
| 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.

### 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.

## ORCID

*Sue Kildea* https://orcid.org/0000-0001-8591-4968

## REFERENCES

1. Dahlen H, Jackson M, Schmied V, Tracy S, Priddis H. Birth centres and the national maternity services review: response to consumer demand or compromise? *Women Birth*. 2011;24(4):165-172.
2. Department of Health Western Australia. *Clinical Guidelines for Women Requesting Immersion in Water for Pain Management During Labour and/or Birth*. Department of Health, Government of South Australia Statewide Service Strategy; 2012.
3. Lim KMX, Tong PSY, Chong Y-S. A comparative study between the pioneer cohort of waterbirths and conventional vaginal deliveries in an obstetrician-led unit in Singapore. *Taiwan J Obstet Gynecol*. 2016;55(3):363-367.
4. UK Healthcare Commission. *Women's Experiences of Maternity Care in the NHS in England: Key Findings from a Survey of NHS Trusts Carried Out in 2007*. Commission for Healthcare Audit and Inspection; 2007:28.
5. Jacoby S, Becker G, Crawford S, Wilson RD. Water birth maternal and neonatal outcomes among midwifery clients in Alberta, Canada, from 2014 to 2017: A retrospective study. *J Obstet Gynaecol can*. 2019;41(6):805-812.
6. Snapp C, Stapleton SR, Wright J, Niemczyk NA, Jolles D. The Experience of land and water birth within the American Association of Birth Centers Perinatal Data Registry, 2012–2017. *J Perinat Neonatal Nurs*. 2020;34(1):16-26.
7. Clews C, Church S, Ekberg M. Women and waterbirth: a systematic meta-synthesis of qualitative studies. *Women Birth*. 2020;33(6):566-573.
8. Lathrop A, Bonsack CF, Haas DM. Women's experiences with water birth: a matched groups prospective study. *Birth*. 2018;45(4):416-423.
9. Ulfsdottir H, Saltvedt S, Georgsson S. Women's experiences of waterbirth compared with conventional uncomplicated births. *Midwifery*. 2019;79:102547.
10. Lanier AL, Wiegand SL, Fennig K, Snow EK, Maxwell RA, McKenna D. Neonatal outcomes after delivery in water. *Obstet Gynecol*. 2021;138(4):622-626.
11. Milosevic S, Channon S, Hunter B, et al. Factors influencing the use of birth pools in the United Kingdom: perspectives of women, midwives and medical staff. *Midwifery*. 2019;79:102554.
12. Australian College of Midwives. *Position Statement on the Use of Water Immersion for Labour and Birth*. ACM; 2013.
13. Royal College of Obstetricians and Gynaecologists, & Royal College of Midwives. *Immersion in Water during Labour and Birth*. London: RCOG & RCM; 2006.
14. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. *College Statement: Water Immersion During Labour and Birth*. RANZCOG; 2008.
15. American Academy of Pediatrics Committee on Fetus and Newborn, American College of Obstetricians and Gynecologists Committee on Obstetric Practice. Immersion in water during labor and delivery. *Pediatrics*. 2014;133(4):758-761.
16. American Academy of Pediatrics, American College of Obstetricians and Gynecologists. *Immersion in Water during Labour and Delivery*. ACOG; 2016.
17. The Society of Obstetricians and Gynaecologists of Canada. Labour in water and water birth. 2020. https://www.pregnancyinfo.ca/birth/delivery/labour-in-water-and-water-birth/ Accessed Xxxx 00, 0000
18. Pinette MG, Wax J, Wilson E. The risks of underwater birth. *Am J Obstet Gynecol*. 2004;190(5):1211-1215.
19. Deans AC, Steer PJ. Temperature of pool is important. *BMJ*. 1995;311(7001):390-391.
20. Burns E. Waterbirths. *MIDIRS*. 2001;11(3):s10-s13.
21. Nguyen S, Kuschel C, Teele R, Spooner C. Water birth–a near-drowning experience. *Pediatrics*. 2002;110(2 Pt 1):411-413.
22. Nagai T, Sobajima H, Iwasa M, et al. Neonatal sudden death due to Legionella pneumonia associated with water birth in a domestic spa bath. *J Clin Microbiol*. 2003;41(5):2227-2229.
23. Coombs R, Spiby H, Stewart P, Norman P. Water birth and infection in babies. *BMJ*. 1994;309(6961):1089.
24. Gilbert RE, Tookey PA. Perinatal mortality and morbidity among babies delivered in water: surveillance study and postal survey. *BMJ*. 1999;319(7208):483-487.
25. Voelker R. More midwife education needed for home water births. *JAMA*. 2015;313(6):559.
26. Cluett ER, Burns E, Cuthbert A. Immersion in water during labour and birth. *Cochrane Database of Syst Rev*. 2018;5:CD000111.
27. Vanderlaan J, Hall PJ, Lewitt M. Neonatal outcomes with water birth: a systematic review and meta-analysis. *Midwifery*. 2018;59:27-38.
28. Geissbuehler V, Stein S, Eberhard J. Waterbirths compared with landbirths: an observational study of nine years. *J Perinat Med*. 2004;32(4):308-314.
29. Mansournia MA, Higgins JPT, Sterne JAC, Hernán MA. Biases in randomized trials: a conversation between trialists and epidemiologists. *Epidemiology*. 2017;28(1):54-59.
30. Aughey H, Jardine J, Moitt N, et al. Waterbirth: a national retrospective cohort study of factors associated with its use among women in England. *BMC Pregnancy Childbirth*. 2021;21(1):256.
31. Bovbjerg ML, Cheyney M, Caughey AB. Maternal and neonatal outcomes following waterbirth: a cohort study of 17 530 waterbirths and 17 530 propensity score-matched land births. *BJOG*. 2021. Epub ahead of print.
32. Bovbjerg ML, Cheyney M, Everson C. Maternal and newborn outcomes following waterbirth: the midwives alliance of North America statistics project, 2004 to 2009 cohort. *J Midwifery Womens Health*. 2016;61(1):11-20.
33. Lewis L, Hauck YL, Butt J, Hornbuckle J. 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. *Aust N Z J Obstet Gynaecol*. 2018;58(5):539-547.
34. Hodgson ZG, Comfort LR, Albert AAY. Water birth and perinatal outcomes in British Columbia: a retrospective cohort study. *J Obstet Gynaecol can*. 2020;42(2):150-155.
35. Papoutsis D, Antonakou A, Gornall A, Tzavara C. The incidence of and predictors for severe perineal trauma and intact perineum in women having a waterbirth in England: a hospital-based study. *J Womens Health (Larchmt)*. 2021;30(5):681-688.

36. Sidebottom AC, Vacquier M, Simon K, et al. Maternal and neonatal outcomes in hospital-based deliveries with water immersion. *Obstet Gynecol.* 2020;136(4):707-715.

37. Thoeni A, Zech N, Moroder L, Ploner F. Review of 1600 water births. Does water birth increase the risk of neonatal infection? *J Matern Fetal Neonatal Med.* 2005;17(5):357-361.

38. Neiman E, Austin E, Tan A, Anderson CM, Chipps E. Outcomes of waterbirth in a US hospital-based midwifery practice: a retrospective cohort study of water immersion during labor and birth. *J Midwifery Womens Health.* 2020;65(2):216-223.

39. Garland D, Jones K. Waterbirth, supporting practice with clinical audit. *MIDIRS.* 2000;10(3):333-336.

40. Otigbah CM, Dhanjal MK, Harmsworth G, Chard T. A retrospective comparison of water births and conventional vaginal deliveries. *Eur J Obstet Gynecol Reprod Biol.* 2000;91(1):15-20.

41. Garland D. On the crest of a wave. Completion of a collaborative audit. *MIDIRS.* 2006;16(1):81-85.

42. Zanetti-Daellenbach RA, Tschudin S, Zhong XY, Holzgreve W, Lapaire O, Hösli I. Maternal and neonatal infections and obstetrical outcome in water birth. *Eur J Obstet Gynecol Reprod Biol.* 2006;134(1):37-43.

43. Cortes E, Basra R, Kelleher CJ. Waterbirth and pelvic floor injury: a retrospective study and postal survey using ICIQ modular long form questionnaires. *Eur J Obstet Gynecol Reprod Biol.* 2011;155(1):27-30.

44. Henderson J, Burns EE, Regalia AL, Casarico G, Boulton MG, Smith LA. Labouring women who used a birthing pool in obsteric units in Italy: prospective observational study. *BMC Pregnancy Childbirth.* 2014;14(1):17.

45. Smith LA, Price N, Simonite V, Burns EE. Incidence of and risk factors for perineal trauma: a prospective observational study. *BMC Pregnancy Childbirth.* 2013;13(1):59.

46. Burns EE, Boulton MG, Cluett E, Cornelius VR, Smith LA. Characteristics, interventions, and outcomes of women who used a birthing pool: a prospective observational study. *Birth.* 2012;39(3):192-202.

47. Dahlen HG, Dowling H, Tracy M, Schmied V, Tracy S. 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.* 2013;29(7):759-764.

48. Royal Hospital for Women Obstetric Clinical Guidelines Group. *Waterbirth and Labour in Water.* RHW; 2011.

49. Department of Health Western Australia. *WA Water Birth Clinical Guidelines.* Health Networks Branch, Department of Health Western Australia; 2017.

50. Department of Health, Government of South Australia Statewide Service Strategy. *First Stage Labour and Birth in Water Clinical Directive.* Adelaide, Australia: Department of Health, Government of South Australia Statewide Service Strategy; 2010.

51. Neonatal and Obstetric Team Guideline Committee. *Intrapartum Guidelines: No.31 Guidelines for Waterbirth.* Plymouth: National Health Service; 2017.

52. Northern Health and Social Care Trust. *Water for Labour and Birth Guideline.* Antrim: Northern Health and Social Care Trust; 2011.

53. Curtin University, & Women and Newborn Health Services. *Women and Newborn Health Service e-Learning Packages: Waterbirth.* Perth, Australia: Government of Western Australia; 2011.

54. Crowther CA, Dodd JM, Hiller JE, Haslam RR, Robinson JS. Planned vaginal birth or elective repeat caesarean: patient preference restricted cohort with nested randomised trial. *PLoS Medicine.* 2012;9(3):e1001192.

55. Bovbjerg ML, Dissanayake MV, Cheyney M, Brown J, Snowden JM. Utility of the 5-minute apgar score as a research endpoint. *Am J Epidemiol.* 2019;188(9):1695-1704.

56. Smith VA, Coffman CJ, Hudgens MG. Interpreting the results of intention-to-treat, per-protocol, and as-treated analyses of clinical trials. *JAMA.* 2021;326(5):433-434.

57. Hernán MA, Robins JM. Per-protocol analyses of pragmatic trials. *N Engl J Med.* 2017;377(14):1391-1398.

58. Scarf VL, Rossiter C, Vedam S, et al. Maternal and perinatal outcomes by planned place of birth among women with low-risk pregnancies in high-income countries: a systematic review and meta-analysis. *Midwifery.* 2018;62:240-255.

59. Hutton EK, Reitsma A, Thorpe J, Brunton G, Kaufman K. Protocol: systematic review and meta-analyses of birth outcomes for women who intend at the onset of labour to give birth at home compared to women of low obstetrical risk who intend to give birth in hospital. *Syst Rev.* 2014;3:55.

60. Baker L, Lavender T, Tincello D. Factors that influence women's decisions about whether to participate in research: an exploratory study. *Birth.* 2005;32(1):60-66.

61. Vernon G, Alfirevic Z, Weeks A. Issues of informed consent for intrapartum trials: a suggested consent pathway from the experience of the Release trial [ISRCTN13204258]. *Trials.* 2006;7:13.

62. Fahy K, Tracy SK. Critique of Cochrane systematic review of home-like setting for birth. *Int J Evid Based Healthc.* 2007;5(3):360-364.

63. Riley RD, Lambert PC, Abo-Zaid G. Meta-analysis of individual participant data: rationale, conduct, and reporting. *BMJ.* 2010;340:c221.

64. Austin PC, Schuster T, Platt RW. Statistical power in parallel group point exposure studies with time-to-event outcomes: an empirical comparison of the performance of randomized controlled trials and the inverse probability of treatment weighting (IPTW) approach. *BMC Med Res Methodol.* 2015;15:87.

## SUPPORTING INFORMATION

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