Universitat de Girona
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FINAL DEGREE PROJECT

SAFETY OF WATER IMMERSION DURING THE SECOND STAGE OF LABOUR IN NON- AND LOW-RISK PREGNANT WOMEN

A MULTICENTER QUASI-EXPERIMENTAL STUDY

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1. ABSTRACT

TITLE: Safety of water immersion during the second stage of labour in non- and low-risk pregnant women

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BACKGROUND: Natural birth consists in giving birth with full control of the body through the vagina. It has been gaining popularity recently as non- and low-risk pregnant women seem to be fleeing from over-medicalised births. More and more women are asking about the option of involving a birth pool on their birth experience, but they don't get the same response in all hospitals: some refuse, others offer to spend the first stage of labour there, and few dare to let them have an underwater delivery. This heterogeneity in supply is due to the dearth of quality data about waterbirth (WB); although water immersion (WI) in the first stage of labour is considered a safe and cost-effective method of pain management, concerns still linger as to the safety of this technique during delivery.
Demonstrating that WB can have minimal complications for both mother and child would eventually mean that the technique is not only physiological and non-medicalised, but also safe. Only in this way will WB become an option available to all women who, once the indication is fulfilled, choose it.

OBJECTIVE: The main objective is to assess the safety of WI during the second stage of labour in women considered to be at non- or low-risk of complications, in a hospital setting. In doing so, the presence of maternal and/or neonatal complication(s) will be taken into account.

DESIGN AND SETTING: This study is designed as a quasi-experimental study, aiming to compare two different modes of natural birth: WB versus landbirth (LB). It will be conducted in 8 different hospitals of different Health Regions over Catalunya.

PARTICIPANTS AND METHODS: 908 participants will be enrolled using a consecutive sampling, and the time of recruitment will be of 1.5 years. Women will be divided by choosing where they want to give birth at the onset of labour, creating this way two groups: the intervention group (WB) and the control group (LB). Data about maternal and neonatal complications, epidural analgesia, prolonged labour and obstetric intervention will be collected after the baby is born and childbirth experience will be evaluated through Childbirth Experience Questionnaire spanish version (CEQ-E) 6 weeks after the delivery.

KEYWORDS: Water immersion (WI), waterbirth (WB), landbirth (LB), natural birth, childbirth experience, birth pool, labour, second stage of labour, safety, delivery, risk

2. ABBREVIATIONS AND ACRONYMS

AAP	American Academy of Pediatrics
AC	Autonomous Community
ACNM	American College of Nurse-Midwives
ACOG	American College of Obstetricians and Gynecologists
AED	Automated external defibrillator
BMI	Body mass index
BP	Birth plan
bpm	Beats per minute
CEIC	Comitè d'Ètica d'Investigació Clínica
CEQ	Childbirth Experience Questionnaire
Comput. Sci	Computer scientist
CPR	Cardiopulmonary resuscitation
CRP	C-Reactive Protein
CTGR	Cardiotocographic register
eCRF	Electronic case report form
FAME	Federación de Asociaciones de Matronas de España
FIGO	International Federation of Gynaecologists and Obstetricians
FSM	Fundació Sanitària de Mollet
GBS	Group B Streptococcus
HC	Hospital coordinator
HCP	Health care professional
HTVC	Hospital de Tortosa Verge de la Cinta
HUJT	Hospital Universitari Josep Trueta
IC	Informed consent
IPN	Iniciativa del Parto Normal
ICU	Intensive Care Unit

LB	Landbirth
MA	Meta-analysis
MI	Main investigator
NB	Newborn
NICU	Neonatal Intensive Care Unit
NRS	Numerical rating scale
NWBG	Non-waterbirth group
OASI	Obstetric anal sphincter injury
OB-GYN	Obstetrics and Gynecology
PPH	Postpartum haemorrhage
PTSD	Post-traumatic stress disorder
SEGO	Sociedad Española de Ginecología y Obstetricia
SENEO	Sociedad Española de Neonatología
SES	Socioeconomic status
SNS	Sistema Nacional de Salud
SR	Systematic review
stat.	Statistician
WB	Waterbirth
WBG	Waterbirth group
WHO	World Health Organization
WI	Water immersion
WG	Weeks of gestation

3. INTRODUCTION

3.1. The importance of birth experience

Childbirth is a **major life event** in a woman's life that has both short and long-term consequences. How a woman **experiences** childbirth is known to have an influence not only on her own health, but also the well-being of her child and other family members.

So much so that a long-term follow-up study found out that a **positive birth experience** is related to an affirmative mother-child relationship and a positive start to motherhood, which at the same time has a strong impact on women's self-confidence and self-esteem throughout their lives (1).

On the other hand, there are unfortunate situations that may occur during childbirth that may convert the process into a traumatic one. **Negative birth experience** has proven to be a risk factor to develop postnatal depression, fear of childbirth and post-traumatic stress disorder (PTSD) (2–4). It is not difficult to realise it is a serious issue as the numbers show: 10% of pregnant women and 13% of new mothers experience an undiagnosed mental health disorder (5).

For all of these reasons, it can be stated that the experience of childbirth forever shapes women's thoughts of themselves and their relationship with her own family (6). Following this idea, according to the World Health Organization (WHO), a **positive birth experience is the primary outcome** for women undergoing labour and being pregnant (7), defined as the one that "fulfils or exceeds a woman's prior personal and sociocultural beliefs and expectations, including giving birth to a healthy baby in a clinically and psychologically safe environment with continuity of practical and emotional support from a birth companion(s) and kind, technically competent clinical staff" (8).

3.2. Epidemiology of childbirth

Globally, it is estimated that 385.000 babies are born each day all over the world, which means about 140 million women give birth every year (9). To be more concrete, 337.380 births took place in **Spain** during 2021 (10). The birth rate during this past year 2022 was 8.014 births per 1000 people (11), and the fertility rate was 1.37 births per woman, meaning that **many women do not only go into labour once** (12).

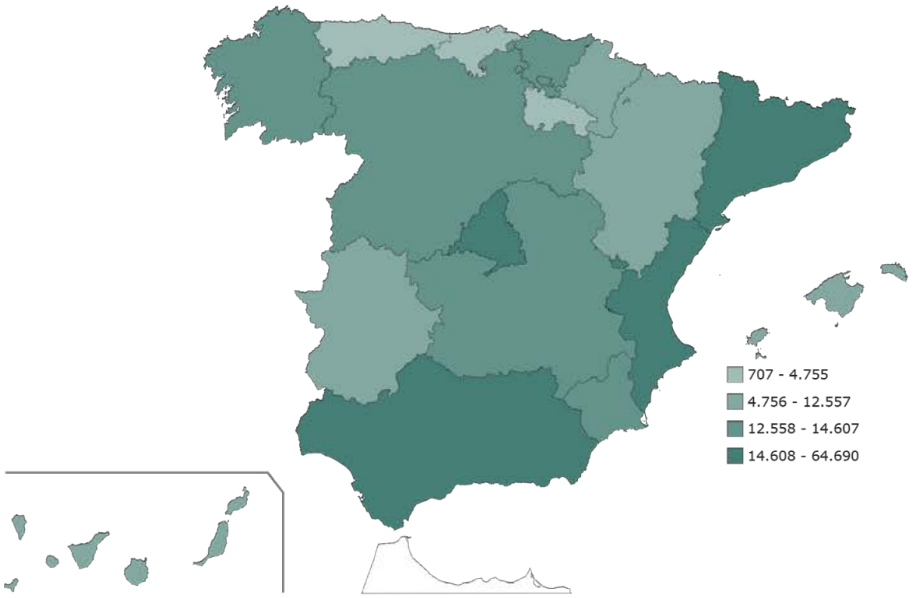

***Figure 1**: Number of births in each Autonomous Community in Spain, 2021* (13).

Not all pregnancies are considered to be of the same **level of risk,** and this is important as will be mentioned later. In 2019, only 7.5% of them were classified as high risk, and the trend in recent years has been downwards, making evident **the vast majority occur without any or very little risk** (14).

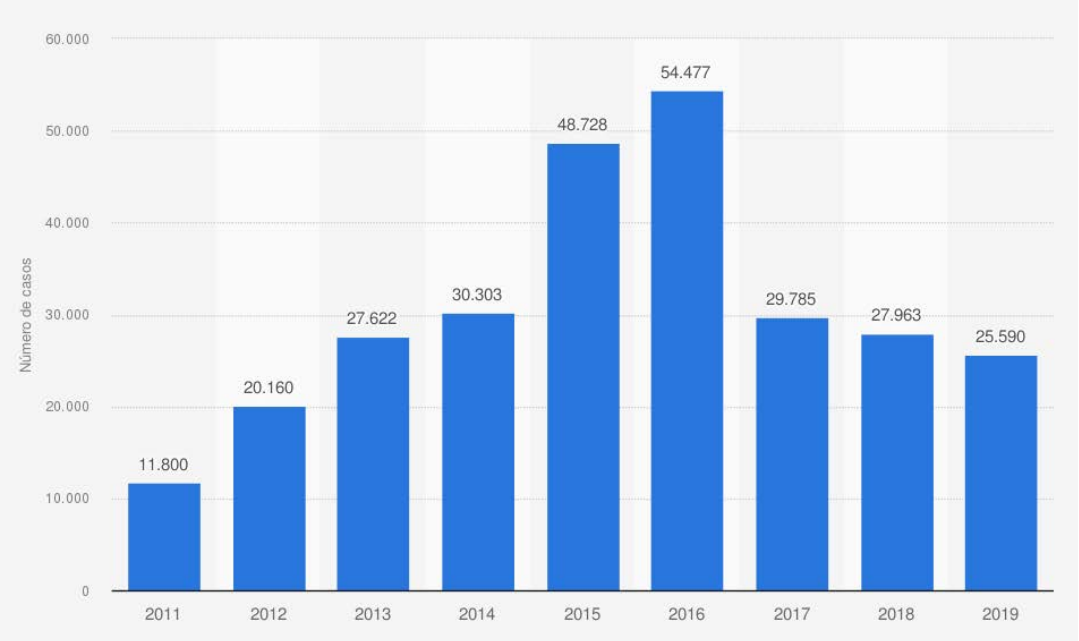

***Figure 2**: Annual evolution of the number of high-risk pregnancy cases in Spain from 2011 to 2019* (14).

The latest data collected in 2021 from **Catalunya** says there were 56.979 childbirths; 25% of catalan women had a caesarean; 66% birthed vaginally whilst in the rest was not reported (15). This demonstrates that **most women give birth vaginally,** but not forgetting that caesarean sections are all too common: 1 in 4 babies are delivered by this technique in Catalunya.

3.3. Childbirth

Definition

Childbirth, consisting of **labour and delivery,** is the ending of pregnancy where the foetus and placenta exit the internal environment of the mother.

Stages

The process is **divided** into three stages:

- **First stage of labour** (8,16): it begins when labour starts and ends with full cervical dilation to 10 cm. It is generally defined with the appearance of regular and painful uterine contractions each 3 minutes, where each contraction lasts 1 minute with an objective change in cervical dilation and/or effacement. It contains two phases which differ on the degree of cervical dilation:
    - During the **latent phase,** the cervix dilates slowly to approximately 5 cm and some degree of effacement is seen. It is considerably longer and unpredictable than the active phase, as it can last up to 20 hrs and 14 hrs in nulliparous and multiparous women, respectively.
    - The cervix changes more rapidly and predictably in the **active phase,** at a rate of 1,5 cm per hour, until it reaches 10 cm and cervical dilation and effacement are complete.

  Women with a history of prior vaginal delivery tend to have a more rapid stage. This idea keeps repeating itself, as the duration of labour depends on the previous experience of the woman's body.

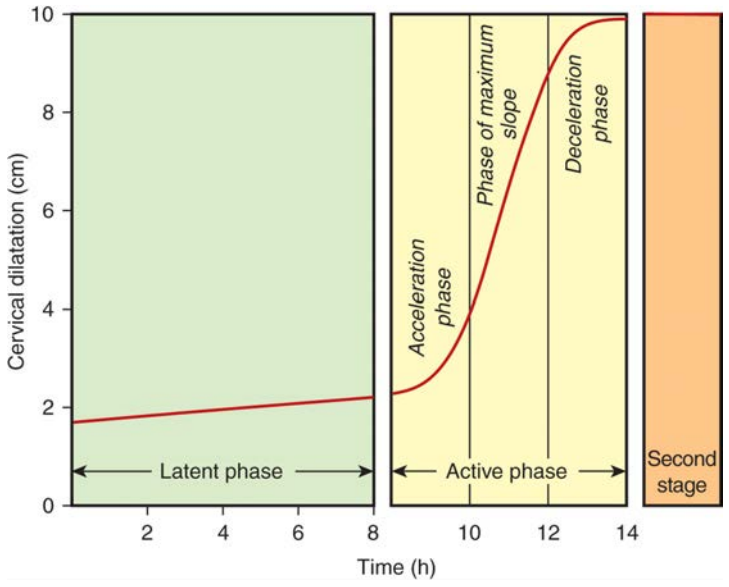

Figure 3: *Composite of the average dilatation curve for nulliparous labour, taking into account the cervical dilatation in cm and time in hours* (17).

- **Second stage of labour** (8,16)**:** it commences with complete cervical dilation to 10 cm and ends with the delivery of the newborn (NB). After cervical dilation is complete, the foetus descends into the vaginal canal through 7 steps that include engagement, descent, flexion, internal rotation, extension, external rotation and expulsion (see ***Figure 4***). These **cardinal movements** allow the baby to adapt to the maternal pelvis while she has an involuntary urge to bear down as a result of expulsive uterine contractions.

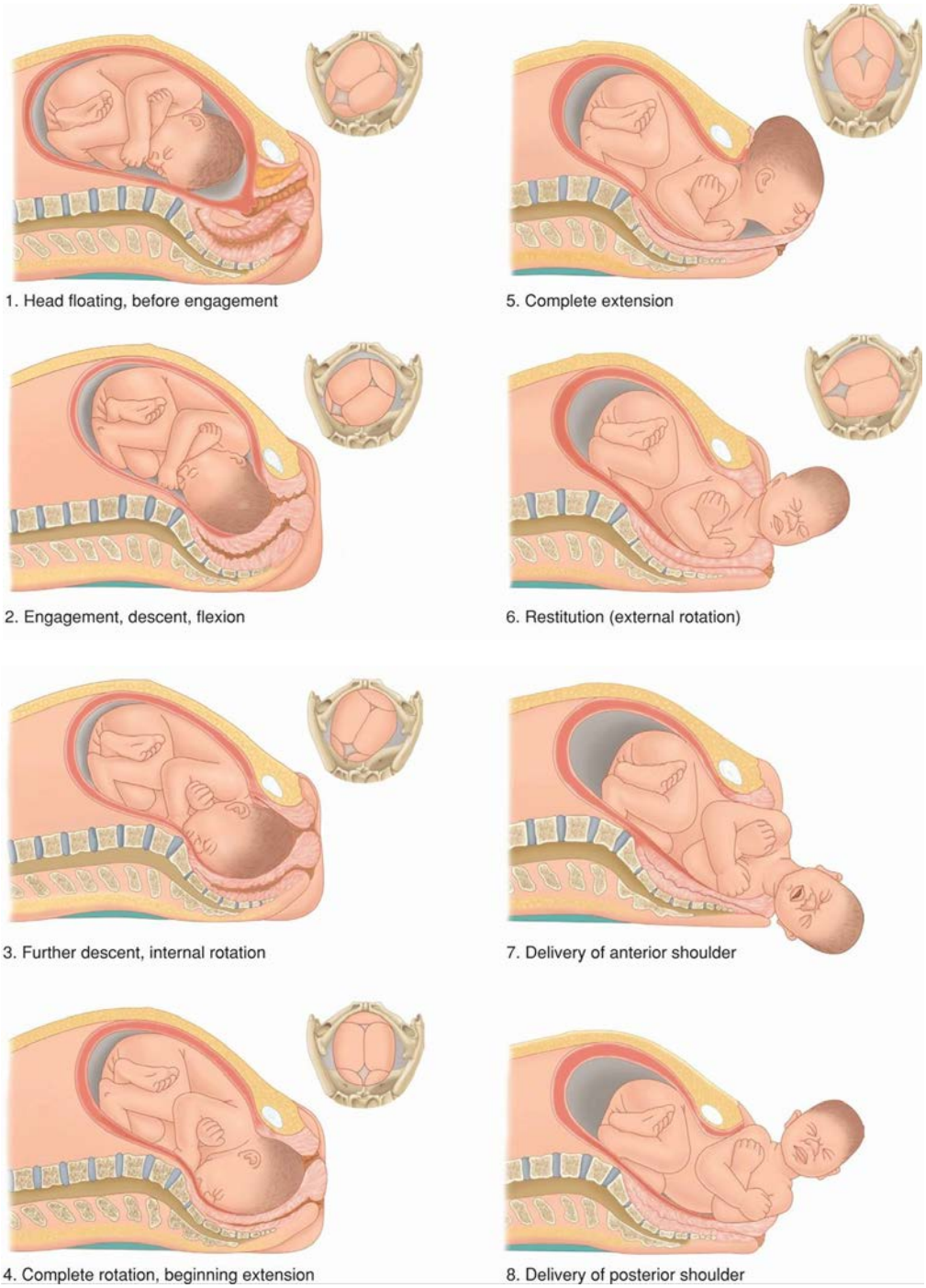

Figure 4*: Cardinal movements of labour and delivery from a left occiput anterior position* (17).

The **level -or station-** of the presenting foetal part in the birth canal is described in relation to the ischial spines, which are halfway between the inlet and the pelvic outlet. When the lower portion of the presenting foetal part is at the level of the spines, it is designated as being at **zero (0) station.** The pelvis above and below the spines is divided into fifths; each fifth represents 1 cm above or below the spines. Thus, as the presenting foetal part descends from the inlet toward the ischial spines, the designation is –5, –4, –3, –2, –1, then 0 station. Below the spines, as the presenting foetal part descends, it passes +1, +2, +3, +4, and +5 stations to delivery. Station +5 cm corresponds to the foetal head being visible at the introitus (17).

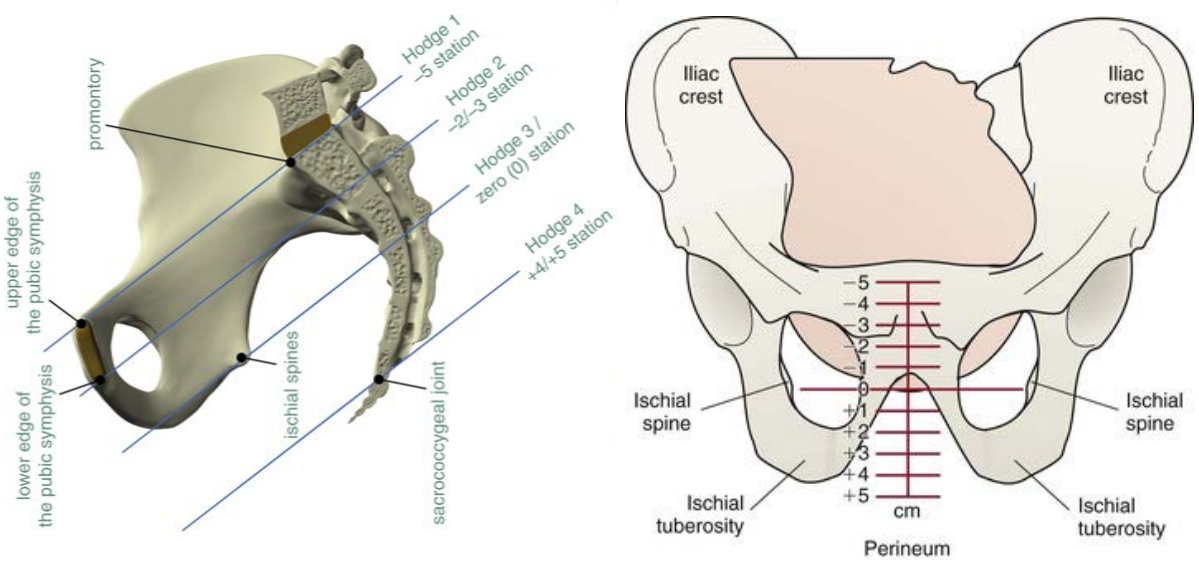

Figure 5: *Hodge planes (left) and stations of presenting part, or degree of descent (right) (18).*

The duration of this phase varies from one woman to another. In first labours, birth is usually completed within 3 h whereas in subsequent labours it can be reduced to 2 h. Anesthesia's administration also has an influence, adding 1 h for each case.

The second stage of labour is considered to be the **most intensive part** of labour for both the mother and the child, seen as a transformative state between pregnancy and motherhood. Research on the overall birth experience has been done, but a fresh study provided insight into this stage in particular; women described it as a "dynamic course of events where moments of fear and vulnerability, doubt and disappointment in one's own ability, coexisted with feelings of power and of being in control" (19).

- **Third stage of labour** (8,16)**:** it initiates when the foetus is delivered and concludes with the delivery of the placenta, which indicates it has been separated from the uterine interface. The process, which includes a gush of blood from the vagina, lengthening of the umbilical cord, and a globular shaped uterine fundus on palpation, may take between 5 to 30 minutes.

Historical framework

The conception of childbirth has changed over time. Until the **middle** of the **20th century,** there was no awareness of the importance of the process, it was **not lived as an experience worth living** to the fullest. Women, with the knowledge based on cultural tradition and inherited from generation to generation, help other women giving birth in the privacy of her home, assisting **without the resources** to deal if a life-threatening situation for mother or NB took place (20).

In the **1960s** a lot of developments occurred: the creation of the *Sistema Nacional de Seguridad Social* with universal coverage, the rapid development of hospital infrastructures, the global economic expansion and the baby boom. It all led to a **transition** from home births to hospital births, with increased technological advances that made NB and maternal mortality decline (21,22).

However, the **physiology of childbirth began to be disrespected,** treating it as just another pathology like the female body was incapable of giving birth with only an expectant conduct. Labour was converted into a **mechanical** process that had to meet certain standardised medical parameters; initiate, accelerate, terminate, regulate and monitor the physiological process makes active management considered the norm (8). This new conception entailed a process of **over-medicalisation** of labour, also known as iatrogenesis, being intervened without always being necessary (20,22,23).

3.4. Normal physiologic labour

Definition

When there is an **absence of complications in the process**, labour is renamed normal physiologic labour. As the *American College of Nurse-Midwives* (ACNM) says (24), it is “the one that is powered by the innate human capacity of the woman and foetus. This birth is more likely to be safe and healthy because there is no unnecessary intervention that disrupts normal physiologic processes”.

The WHO defined normal birth as "**spontaneous in onset**, **low-risk** at the **start** of labour and **remaining** so throughout labour and delivery. The infant is born **spontaneously** in the vertex position between **37 – 42 completed weeks of gestation (WG)**. After birth, mother and infant are in **good condition**" (25).

Non- and low risk pregnancy

The objective of **risk assessment during pregnancy** is to predict which women are most likely to experience adverse health events, and thus be able to focus material and human resources to those who need them most. Consequently, this entails not overusing technology and unnecessary interventions, leading to better care, better health, and lower cost (26).

In Catalunya, there is an extensive protocol on the follow-up that needs to be done for each type of pregnancy, after having assessed each woman to a risk, based on numerous characteristics (27). To summarise, the attributes defining each risk group are listed in an annex to this protocol (see ***ANNEX 1***). In general, women with **'non-risk' and 'low-risk' of pregnancy are considered to have the highest chance of having a normal birth, attended by midwifery care** (25)**.**

Management

Is a great truth, as Hutchison J (et al) says (16), that the "management of low-risk labour is a delicate balance between allowing the natural process to proceed while limiting any potential complications".

During labour, the patient should be placed on **cardiotocographic register (CTGR)** to control uterine contractions and foetal heart rate over time in order to identify any signs of foetal distress or inadequacy of contractions that would warrant obstetric intervention. The minimum **cervical examinations** required and **vital signs of the mother**, including temperature, heart rate, oxygen saturation, respiratory rate, and blood pressure, are taken every few hours if there is no concern to bring it forward. Women should be allowed to **ambulate freely** through the room and hospital corridor, be accompanied, change positions if desired and oral intake should not be forbidden.

3.5. Disrupting the normal process

There are situations that make what seemed easy and straightforward become complicated and turbulent. Countless complications can transform what was previously considered a 'non or low-risk' birth, with no indication for intervention, into an '**intermediate or high-risk' birth,** requiring obstetric assistance.

The aim of care in normal birth is "to achieve a healthy mother and child with **the least possible level of intervention that is compatible with safety**. This implies that in normal birth there should be a valid reason to interfere with the natural process" (25).

Complications

- **Perineal or vaginal tears:** they occur when the baby's head is coming through the vaginal opening and is either too large for the vagina to stretch around or the head is a normal size but the vagina doesn't stretch easily. They can be classified according to the structures affected, from less to more severe (28):
    - **1st and 2nd-degree:** the first involves the skin between the vaginal opening and the rectum (perineal skin), and the second one occurs when the perineal muscle is compromised in addition to the skin. The symptoms are minimal: mild pain or stinging during urination. They don't require stitches and typically heals within a few weeks.

- **3rd and 4th-degree:** together they are also known as **obstetric anal sphincter injuries (OASI).** The former is defined when the laceration affects the muscle surrounding the anus (anal sphincter), while the latter adds the extension into the mucous membrane that lines the rectum (rectal mucosa). Both require repair with anaesthesia in an operating room and might take months to heal. They lead to complications such as faecal incontinence and painful intercourse. Clinical diagnosis of OASIs occurs in about 0.8-11% of women depending on parity, decreasing the incidence with subsequent births (29,30).

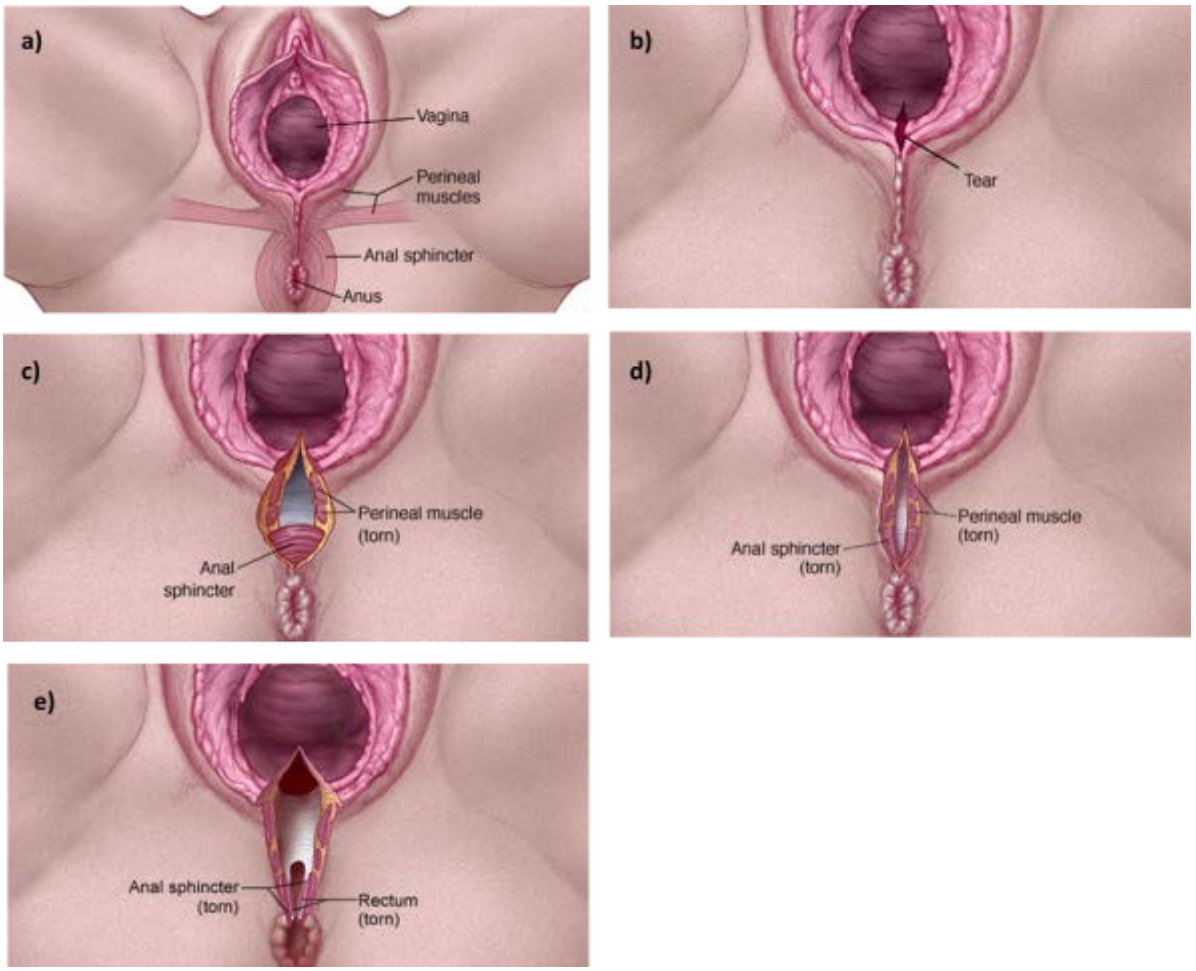

***Figure 6**: Classification of perineal tears. a) Perineal anatomy b) 1st degree vaginal tear c) 2nd degree vaginal tear d) 3rd degree vaginal tear e) 4th degree vaginal tear* (28).

- **Early postpartum haemorrhage (PPH):** cumulative blood loss of greater than or equal to **1,000 mL** or blood loss accompanied by **signs or symptoms of hypovolemia within 24 h** after the birth process. It remains the leading cause of maternal mortality worldwide, causing every year about 70,000 maternal deaths out of 14 million women affected, representing 5-10% of all births (31–33). Although the postpartum period lasts until day 42, early PPH is a major cause of postpartum mortality (34).

- **Maternal peripartum infection:** it is an important, preventable cause of maternal morbimortality, with estimated rates of 4% in labour (35). WHO defines this complication as "a bacterial infection of the genital tract or its surrounding tissues occurring at any time between the onset of rupture of membranes or labour and the 42nd day postpartum in which two or more of the following are present: pelvic pain, fever, abnormal vaginal discharge, abnormal smell/foul odour discharge or delay in uterine involution" (36). Several pathologies are included in the definition: **chorioamnionitis**, which is the infection of the placenta, membranes and/or amniotic fluid, and **endometritis**, which is the inflammation of the endometrium (the inner lining of your uterus) due to infection.
- **Shoulder dystocia:** occurs in 0.6-0.7% of vaginal deliveries, with the incidence increasing to 5-7% in the case of macrosomic babies (>4000g). It is caused by **impaction of one or both foetal shoulders on maternal pelvic structures**, being the anterior shoulder impaction at the pubic symphysis the more common one. It is an unpredictable and preventable obstetric emergency, requiring complex manoeuvres to disimpact the impacted shoulder. It can lead to maternal and neonatal complications, or have no repercussions at all (37).

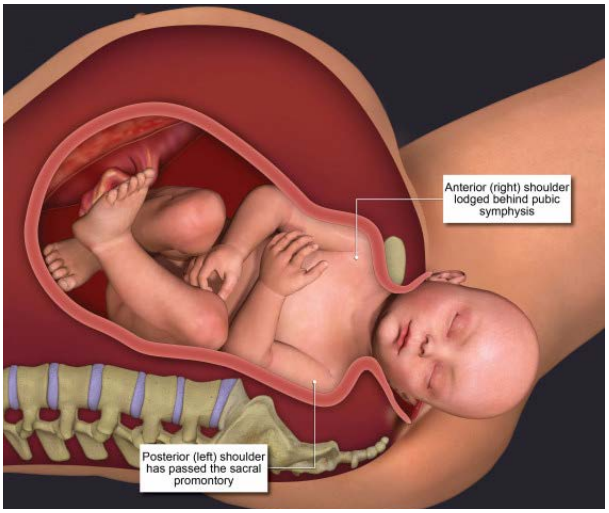

***Figure 7**: Graphical representation of an anterior shoulder dystocia seen from a sagittal plane* (38).

Interventions

- **Caesarean delivery:** it is used to deliver the baby through surgical **incisions** made firstly to the abdomen wall, and secondly to the **lower part of the uterus**. The aim is to get the baby out quickly when it is in distress or when passage through the birth canal is physically impossible, serving as an example when the placenta covers the opening of the cervix (placenta previa) (39).
- **Instrumental vaginal delivery:** also called assisted or operative birth, is the vaginal delivery accomplished with the aid of instruments, which are placed on the baby's head and used to extract from the vagina. It can be done by a **vacuum cup** or **forceps** (40).

- **Episiotomy**: an **incision** made during birth in the **perineum** with the objective of preventing larger vaginal tears, as an incision wound is known to heal better than a natural tear (41).
- **Induction of labour**: is prompting the uterus to contract before labour begins spontaneously to achieve a vaginal delivery. Two reasons that could justify the intervention would be when there's not enough amniotic fluid surrounding the baby (oligohydramnios) or the nearing 1 to 2 weeks beyond the due date without labour starting (postterm pregnancy) (42).
- **Augmentation for labour**: is stimulating the womb in order to increase frequency, duration and intensity of uterine contractions after the onset of spontaneous labour. It is a way of resolving **prolonged labour**, which occurs when, once the active phase of labour has begun (cervical dilatation ≥4 cm) and with adequate uterine dynamic, there is no change in obstetric conditions after 4 h or 3 h in nulliparous or multiparous women respectively (43).

3.6. Increasing concern about women's participation in giving birth

Despite mounting evidence-based studies that prove the benefits of normal birth, there has been a **substantial increase** over the last two decades in the **application of labour practices**; the epidural rates and the number of caesareans are rising lately (reaching almost 25% in Spain) (6), and a substantial proportion of healthy pregnant women undergo at least one clinical intervention during labour and birth (8).

The progressive over-medicalisation process meant the loss of **women's autonomy** and protagonism in childbirth itself (20). Their decision-making was practically annulled, which negatively impacted her childbirth experience and led even to traumatic experiences (19,22).

Subsequently, the lasting situation contributed to a growing demand for an **improvement in childbirth care**, hoping that professionals who accompany the mother and baby will do so in a personalised and up-to-date way, avoiding excessive medicalisation, in accordance with the natural physiology of the process and respecting the autonomy of the woman (22).

To make tangible changes, various organisations and the Spanish and European legislation implemented laws and documents in relation to labour:

- In Spain, the current ***Ley de 41/2002 de autonomía del paciente*** (44) guarantees the right of every woman to decide freely about her health. The woman, conceived as an adult and responsible person, has the right and the capacity to make decisions after receiving adequate information, among the available clinical options regarding childbirth. This idea is similar with **choosing freely where to give birth,** which has been recognised by the WHO since 1997 and is also a right collected by the *International Federation of Gynaecologists and Obstetricians* (FIGO).

- Likewise, the *European Court of Human Rights* affirms that every woman has **the right to choose the circumstances and the setting in which she wishes to give birth** or the type of care she wants for her pregnancy, birth and postpartum, based on her knowledge, intuition, experiences, values and beliefs, and also the duty to accept personal responsibility for these decisions. Therefore, every European state should ensure women's access to the mode of birth she wants and should establish the necessary measures to guarantee maximum safety (20).
- In 2007, the *Federación de Asociaciones de Matronas de España* (FAME) launched the *Iniciativa del Parto Normal (IPN)*, which included the establishment of a **birth plan (BP).** The BP is a written document in which the pregnant woman states her preferences and **expectations** about the process she is about to live (see ***ANNEX 2***), this way opening communication with the professional team attending the birth and thus help to make the consent process truly informed. It is not superfluous to point out that **to be eligible for the BP,** it is essential that the pregnancy and delivery **be considered non- or low-risk at all times** (45).

For all the arguments specified above, there has been greater focus on finding out how best to facilitate **physiological labour and birth** with support from non-invasive, non-pharmacological interventions but still be able to fulfil the desire to be an active participant of the process and achieve a positive experience. This new request compels experts to review labour and delivery practices that can achieve these goals, and this is where the role of **water immersion (WI)** comes in (46).

3.7. Water immersion

Definition

As the last meta-analysis (MA) defines (47), "WI in a birth pool can be divided into two distinct but overlapping categories:

- **WI during labour** involves using the pool during the first stage of labour but coming out of it for the birth. With this practice, the infant emerges into air to breathe. Its analgesic effect, as will be mentioned later, leads to it also being called **hydrotherapy** or **aquatic therapy.**
- **With waterbirth (WB)**, the woman remains in the birth pool throughout the second stage of labour, with the NB emerging into the water".

For the purposes of this study, and to understand what type of birth it is being compared to, the terms **landbirth (LB) or conventional birth** are used to refer to any form of childbirth other than WB, in which the baby is born on dry land.

History

The use of WI as a therapeutic method is not new; there is evidence of its use since the time of Greeks and Romans. But it was not until **1805** that **the first documented WB occurred**, in France (48).

For today's generation of mothers, the key figure in the use of water for labour and birth is the French obstetrician **Michel Odent.** In 1977, Odent installed a pool in the hospital at Pithiviers and began to systematically put women in a bathtub during childbirth. It was not with the idea of promoting birth in water, but as an additional option for pain relief. He published his findings in *The Lancet* and his recommendations provided the basis for the first midwifery guidelines for WB, in 1983 (48).

The medical establishment called the practice into question, citing theoretical risks of infection and fears of the baby drowning. It was not until **Paul Johnson**, a neonatal physiologist, described the physiology breathing in the NB in 1996 that such fears were appeased (48).

The WB movement gained traction with the publication of "Birth Without Violence" (1975), which states women are attracted to water for the benefits of relaxation, comfort, pain relief and control over their births (48). It became more popular in the 80s and 90s, leading to the point where more than 150,000 WB were registered between 1985 and 1999 globally (49).

Currently, one well-known figure who is fighting to implement WB is **Barbara Harper,** who last May implemented the "Parto en el agua" course at the Hospital de Palamós (50). She is also the founder and director of *Waterbirth International*, a centre that has been promoting and researching WB and gentle birth since 1983.

Indication

Women who are willing to envelop water in her childbirth must be at non or low-risk because as the level of risk increases, so does the likelihood of needing an intervention that, due to discomfort or greater difficulty, cannot be carried out in the water. This is how the chairman of the Obstetrics and Gynecology (OB-GYN) department at Oregon Health and Science University puts it: "If you have to do an emergency C-section, it would be foolhardy to risk an extra 4 or 5 minutes to move you out of the water" (51).

3.8. Collection of evidence on water immersion

3.8.1. Benefits

1) Analgesic effect

The basis of WI is the analgesic effect that the liquid element has on uterine contractions, which tend to be painful. The physiology behind this conception is simple: water at a temperature of 37 degrees releases **endogenous endorphins**, the body's natural pain relievers, and therefore it directly reduces pain. It is therefore easy to assume that the **request for epidural analgesia is decreased** (47), and subsequent risks associated with this drug (52).

Numerous studies endorse this effect (47,53,54), reporting water to be not only analgesic but **soothing and comforting** (53). So much so that warm WI is a non-pharmacological method for labour pain relief that has been presented in the *Estrategia Nacional de Salud Sexual y Reproductiva del SNS* since its 2011 edition (55), and it is also contemplated in the clinical guideline last updated 2022 **only for first stage of labour** (56).

2) Ease of movement

This technique generates a **sensation of lightness** created by water itself. A recent study indicates that buoyancy enhances freedom and unrestricted movement, so finding a comfortable position is more likely (46). The birthing pools provide a space where the woman can adapt and influence to best suit her individual needs (54).

3) Increased satisfaction

Of the few studies that have taken into account women's experiences of using WI, there has been an **overwhelmingly positive response**. It has been seen because it nearly doubles the satisfaction (Odds ratio = 1,95) when compared to LB (47), and obtains higher rate by Childbirth Experience Questionnaire (CEQ) scores (57) or a numerical rating scale (NRS) from 0 to 10 (58).

Satisfaction gains credibility when it can be compared with similar experiences. In this sense, a recent study highlights that women who used water **rated their childbirth experience higher** compared to previous experiences not involving water (46). This is in line with another study, where 72% of the women 'entirely agreed' that water utilisation facilitated a positive birth experience while more than 85% suggested that they would recommend WI to others (46).

4) Greater sense of control and relaxation

The warmth of the pool, maintaining ambient lighting and minimising distractions and stimulation can reduce the release of catecholamines, the stress hormones, and provide **relaxation** (53). This leads to an increase in focus and greater sense of **control** over their body (58). This is not dissimilar from the finding of a previous study, which concluded that women who were dissatisfied with obstetric previous practices aspire to **express their autonomy** by choosing WB over other options (59).

Some others did not find that water completely removed the labouring pain, but furnished the woman with greater ability to cope with it by stimulating a "mind-body connection that enhanced feeling of **control**, self-efficacy and self-trust" (54).

Beyond the properties of water, the birth pool receptacle itself is of importance too, as it demarcates a space created by the structure sometimes described as a 'cocoon', 'safe haven' (53) or 'home-like' (46), making women report feelings of **safety, privacy and security** (54).

5) Less perineal tears

Women giving birth in water had a **lower risk of second-degree perineal tears** (58). A reasonable explanation for this could be the positive effect of warmth in the perineum, leading to vasodilation and increased blood supply (58).

That is not discerning from the results obtained when 17 studies were encompassed; the analysis favoured WI when talking about the outcome 'intact perineum' with an Odds ratio = 1,47. It is worth highlighting that subgroup analysis revealed no difference in odds in midwifery-led settings but higher in obstetric settings (47). One reason to explain this is that the midwives' management of the second stage in WB is often described as more 'wait and see' following the 'hands-off' technique, which could have a protective effect (58).

Conclusions according to stages

It should be understood that outcomes associated with WI at the first stage of labour do not necessarily coincide with outcomes when underwater delivery occurs. Therefore, it is decided to estimate the benefits taking into account in which stages of labour the belly is kept under water.

When talking about the **first stage of labour,** a systematic review (SR) concludes that WI decreases requirement for epidural analgesia and shortens delivery duration, but it does not have an impact on the number of normal vaginal birth, instrumental birth, caesarean section, serious perineal tear and neither NBs being admitted to Neonatal Intensive Care Unit (NICU) or developing infections (52). On the contrary, another study which examined potential factors associated with normal physiologic

birth, affirmed that a high proportion (n = 5,758 = 71.4%) of women who laboured in water had no interventions, supporting the idea that WI favours normal physiologic birth (60). In short, **the advantages of WI during the 1st stage of labour are well described** in the literature since abundant studies resulted in favouring this option when compared to land.

As regards the **second stage of labour,** women benefited positively from the support and relaxation of the water during the pushing phase, which increased their sense of control (54). However, no significant difference was found for the following variables: mode of birth (spontaneous birth, instrumental vaginal births and caesarean sections), perinatal death, admission to NICU, neonatal infection, postpartum haemorrhage (PPH), duration of labour or APGAR score (52). In contrast, the latest MA did find reduced use of episiotomy and higher odds of intact perineum (47).

In relation to the **third stage of delivery**, there are no studies that provide comparison data for third-stage management (47).

Summarising, there is **no** data explained above to show **neonatal benefits** associated with WI. In conclusion, if one sentence were to summarise this information, it would be **'undoubtedly maternal benefits'.**

3.8.2. Adverse effects

1) Water contamination and resultant infections

Water contamination has been described when samples from the tap and from the water discharge system of the tubs used for WB are collected. An Italian study found out the presence of *Staphylococcus spp* and *yeasts,* and a German article also highlights the appearance of *Escherichia coli* and *colibacilli* due to the faeces that are discharged into the birthing tub during pushes.

NB have been reported to **have died from severe respiratory involvement or sepsis** due to *Pseudomonas aeruginosa* (61,62) and *Legionella pneumophila* (63) after being delivered in a birth pool. These infections are usually of nosocomial origin and although is a rare cause of neonatal pneumonia, it presents a high mortality rate of 50% in children younger than one year. Moreover, the **major natural reservoir** for the second bacteria **is contaminated water** that could be found at various stages of a NB's hospitalisation, particularly the pool water (63).

2) Water inhalation by the newborn and possible implications

Under normal conditions, NBs immersed in water at birth do not aspirate water due to the presence of the **"diving reflex",** which works with automatic glottis closure during immersion. Following this idea, NB starts respiration when exposed to cold air (64).

However, there is clinical evidence **this reflex can be abolished in conditions of foetal compromise,** inadequate temperature of the water or maternal anaesthesia, initiating the respiration and gasping reflex early, when still submerged, with the consequent aspiration of water (61,65). The described sequelae are not only increased risk of infection, but also **severe ionic disturbances like hyponatremia, even translating into seizures** that required admission to the NICU (62,66).

3) Higher rates of umbilical cord avulsion

Cord snaps and the subsequent haemorrhage associated with WB could be related to undue traction exerted on the umbilical cord as the baby is brought to the surface, as the distance seems to be greater than in land-based birth and there is a strong instinct to bring the NB above the surface immediately (67,68).

This outcome was the only one **favouring standard care** in the already mentioned 2022 MA (47) as well as in other studies (58,69). Likewise, a review observed 1 avulsion in every 288 WB compared with 1 avulsion every 1,361 LB (67).

The clinical consequences of this complication remain unclear; while none of these neonates required blood transfusion or admission to NICU in a comparative study (58), another speaks out 23% of the cases lead to NICU admission and 13% required transfusion (68).

4) Thermoregulation and foetal compromise

The water temperature of a birth pool should never exceed her natural core temperature. When maternal temperature increases, there is a concomitant rise in metabolic activity and oxygen demands which may be seen in **foetal heart rate changes,** and which may contribute to foetal compromise during labour, associated with **foetal mortality and morbidity** (67).

5) Desacceleration of the labour process

The time of entry into the immersion pool matters: early entrance, understood as entering the birth pool before a cervical dilatation of 5 cm, is related to **higher rate of augmentation and use of analgesia** when compared to the late immersion (70). Conversely, there is also evidence to suggest WI can augment labour, like a Swedish comparative study which counted an average of 1 h less of labour in the waterbirth group (WBG) (58).

There is a known relation between longer duration of active labour and negative childbirth experience (71), so giving longer duration to water labour versus land labour is an unfavourable item.

Conclusion

The available evidence does not suggest an increased risk of adverse neonatal outcomes with WI during the first stage of labour, but there are **reported cases of serious problems and death in connection with expulsion.**

For curiosity, "What are the benefits? Are they concerned? Women's experiences of water immersion for labor and birth" (46) is a study made in 2019 with the aim of determining women's experiences and perceptions related to WI for labour and/or birth. They found out that women's **concerns do not align with the commonly cited adverse events** in the literature, but were most concerned with the possibility of being told to get out of the water when they did not want to, and that staff would not support their choice.

3.9. Current situation regarding water immersion

Inequitable access to birthing pools

In Australia and the United Kingdom, WI and WB is recognized as an option for healthy women with uncomplicated pregnancies. However, it is difficult to have the opportunity to give birth in water in the United States or Canada (69).

Differences in access to birth pools have been found according to ethnicity and socio-economic status of the pregnant women; WB is **less likely in women of Black or Asian ethnicity,** who are of ethnic minority origin, as well as it with increasing **socio-economic deprivation** (7.7% in the most deprived areas compared to 18.9% in the most affluent areas) (72). Similarly, a study in 2014 already spoke of the direct relationship between the use of WI for childbirth and economic status, and that **women who did not understand the language** or were **unsupported by their partner** were less likely to choose the option too (73).

These disparities reflect that those groups are less empowered and therefore less able to advocate for their own preferences during labour and birth. Therefore, **access to birthing pools is not equal even in those countries where it is practised** (72).

The option in Spain and Catalunya

This past October 2022, a SR was published in which data on the use of bathtubs in the delivery area of *Sistema Nacional de Salud* (SNS) hospitals was studied (74).

According to the results, out of 278 public hospitals in the SNS offering Gynecology and Obstetrics care, **WI during labour is offered in at least 46 hospitals** in 13 Autonomous Communities (ACs), including Catalunya; this means that **only 16.5%** of Spanish hospitals **have the material resources** to provide it (74).

It is worth mentioning that there exists **variability in the offer** of this mode of birth among those same hospitals; all of them offer the bathtub during dilatation, but only 32% keep the offer during the second stage of labour and 15% during delivery of the placenta (74).

***Figure 8**: Percentage representation of birth stages where water immersion is offered. WI: water immersion.*

This concept is reflected in the **protocols** of the respective centres; both the Hospital Clínic de Barcelona and the Hospital Santa Caterina (Salt) offer WI, but in very different ways. For example, in the former it is found that "assistance to the expulsion in the water will only be used in cases where the expulsion is precipitated and/or there is not enough time to get out of the bath or to empty the water from the tub" (75). In contrast, the second has been delivering babies through a birth pool for more than 10 years.

Another idea is that not every hospital has the same **years of experience** with the use of the baths; 20% have more than 10 years, 45% are between 5-10 years and the rest less than 5 years (74).

The **challenge in finding numbers** related to WI during childbirth in Spain is real; 35% of the same public hospitals that offer it confess not keeping a register (74) and there exist private centres with records not available for consultation. In addition, home births are known to happen but it is hard to keep a tally.

Reasons and consequences of the disparity

Why is there so much disparity in the supply of underwater birth? Why are there hospitals that consider that the expulsion is the right time to exit the tub? The answer is simple.

At present, in view of the lack of scientific evidence of any benefit and the absence of safety data as regards health of the NB, in addition to the existence of documented clinical cases with severe complications or fatal evolution, the *Sociedad Española de Neonatología (SENEO)* endorsed by the *Sociedad Española de Obstetricia y Ginecología (SEGO)*, recommends since 2015 that **this mode of delivery should only be considered in the context of a controlled clinical tria**l (61).

This consensus opinion between the two most important societies in Spain representing the two specialties related to this practice, is not very dissimilar from the opinion of American societies.

The *American College of Obstetricians and Gynecologists* (ACOG) together with the *American Academy of Pediatrics (AAP)* wrote their joint opinion in the Committee Opinion on Obstetric Practice (76). They reaffirmed in 2021 the last sentence with which it ends: “until neonatal complications incidence is determined in population-based analyses, **it is the recommendation of the College that birth occur on land, not in water”.**

In addition, it states in writing that “even if a woman asks for this type of delivery, if the physician believes, based on evidence, that second-stage immersion and giving birth while submerged would be detrimental to the overall health and welfare of the woman or the foetus, he/she should not perform such a delivery” (76). This highlights another disadvantage: the lack of evidence-based guidelines regarding WB can lead to **malpractice allegations against providers** if complications arise. When suing, courts are likely to hold physicians and facilities liable if the decision-making pattern leading to the choice of WB is flawed, not clearly defined and not adequately documented (64).

Controversy began in 2014, when this recommendation was published simultaneously with the official communication of the ACNM, which says **"WB and expulsion can be safely offered to women without risk factors".**

3.10. Need for further research

The debate regarding WB is still open

Despite evidence of positive outcomes and little to no evidence of adverse events, **WI remains a controversial option, particularly for birth** (52). Though WI in the first stage of labour is generally considered a safe and efficient method, researchers vary in their conclusions about outcomes related to WB compared to other modes of birth (46).

Whereas powerful studies stay clear in the idea that water delivery should not be considered as standard clinical practice due to its possible potentially neonatal complications (64), others remain clear in their belief that WI during the second stage of labour is a safe practice (47).

Diverse study designs and methods, and contradictory research findings create **difficulty in synthesising outcomes** to inform clinical decisions and thus **implement evidence-based guidelines** (47). Accordingly, government policy and professional guidelines in different countries vary in their support for WI.

Adverse NB outcomes that are a consequence of WI are **rare but potentially very serious**, which could increase if the use of WI gets trendy. Even though few studies reported them, and data arise predominantly from individual case reports with marginal statistical significance (64), it does not usually go unnoticed and in fact it is often **an argument** that many professionals, especially paediatricians, **use to reject this option** (46): "Although very few, there are cases of waterbirth where children have developed infections and pneumonia due to aspiration of germs that tend to proliferate better in an aqueous environment, such as Legionella, for example," says José Ramón Fernández, a neonatologist paediatrician at the Santa Lucía Hospital in Cartagena.

Consequently, there is keen interest in reliable research evidence comparing maternal and NB outcomes by modes of birth. This is seen in the conclusion of several studies, that leave written there remains a **need for further research** to consider the **safety and benefits of WB** (46,60,64,69,77), specifically with large collaborative trials or conducting well-designed prospective studies to answer this critical issue (52,74).

Aim of the study

Any woman contemplating WB will regard the safety of her infant as of paramount importance. For some, these case reports will be sufficient in their decision to decline the option, while others are prepared to trade off a small risk of a very serious outcome against the perceived benefits of the experience. To make this decision a little easier, women deserve to know **whether or not WB is a safe practice.** The answer remains uncertain, and **the aim of this study is to address this important concern.**

In the hope of achieving a positive outcome, this study is intended to assist in the creation of a **common action protocol** for all SNS hospitals, the offer of **continuous training to professionals** on this method, the **creation** of **infrastructures** to make it possible and the **dissemination of this resource** among **all non- and low-risk pregnant women**.

4. JUSTIFICATION

Childbirth is an important and **prevailing existential life-event,** with both short and long-term consequences on women's life.

In recent decades, the **growing demand** by the population and professional groups for care based on respect for the **physiology of childbirth** has made it mandatory to seek for care based on scientific evidence aimed at promoting the **participation of women** in informed decision making, with **minimal obstetric intervention** and **avoiding excessive medicalization** during childbirth.

In this sense, the search for alternative measures to epidural analgesia to increase women's autonomy and well-being during childbirth is one of the objectives to be achieved. Among other measures, the use of **WI as a non-pharmacological method** for pain relief is offered in some SNS hospitals, and a few have ventured to **install birthing pools** in the maternal and infant area.

The use of WI during the **first stage of labour** is a great comfort measure, inexpensive and effective. It can undoubtedly provide maternal benefits, especially in terms of pain relief and also low episiotomy and induction rates (47). And most importantly, it is considered a **safe option for non- and low-risk pregnancies** as no neonatal or maternal complications are proven (64).

On the other hand, data on WI during the **second stage of labour** is **controversial,** especially with regard to safety for the NB. Data on neonatal risks arise predominantly from individual case reports, observational studies and case series, with marginal statistical significance. However, although these problems are rare, they are known to be **potentially serious and even fatal.** Exposing the NB to potential harm, even if it is infrequent, should be the subject of much reflection, and even more so if there are no proven benefits for him/her. Moreover, the decision-making process needs to take into account a key element: **the legitimate wish to limit the medicalization of birth to a minimum cannot come at the expense of safety** (64). Not everything goes to obtain a positive childbirth experience.

The latest SR and MA on the subject are in favour of WI during expulsion, but **prominent scientific societies**, like the SEGO and AEP, agree that available evidence is limited and therefore they classify the option as **unsafe**. This heterogeneity in results and opinions is reflected in the **disparity of delivery protocols** of the different hospitals in **Spain**. Of those few that offer the option, only a third take the view that WI is a safe form for the expulsion and see it as standard clinical practice. Thus, **not all women living in the country have the same choice** between a WB and a conventional birth.

It is urgent to get **high-quality safety data** regarding the risks of WB, as the lack of evidence-based guidelines and recommendations can lead to **malpractice allegations** for providers in case of adverse outcomes for the mother and/or the NB (64).

Because of women's interest in alternative birth methods, midwives, obstetricians and paediatricians should stay abreast of the latest research evidence and professional guidelines surrounding WB (49). In arriving at a clear conclusion, a **common protocol for action** should be created and **providers should be trained** on this procedure. And last but not least, WI should be **included in the BP** to ensure all non- or low-risk pregnant women, regardless of where they live, where they come from or their socioeconomic level, have the same possibility to opt for WI during childbirth in a safe and satisfactory manner (74).

In conclusion, concerns persist regarding the safety of second stage immersion and the greatest challenge is to **keep the satisfaction rate high while ensuring safe outcomes for both the mother and the child.** Only in this way can it be as valid a way of giving birth as the one we all know.

5. HYPOTHESIS

The assumptions leading to the start of this study are as follows:

5.1. Main hypothesis

Non- and low-risk pregnant women who have underwater delivery suffer fewer maternal and foetal complications than those who deliver on land, proving to be a safe practice.

5.2. Secondary hypotheses

1. **Immersion in water during childbirth will give women a better childbirth experience** than those who do not involve water in the process, resulting in a **higher Childbirth Experience Questionnaire-E score.**
2. **Women who labour in water request less epidural analgesia** in comparison to those who labour on land.
3. **Fewer prolonged labour are observed when women enter the water to labour** versus those who do not.
4. **Immersion in water during delivery requires less obstetric intervention** compared to women who deliver outside.

6. OBJECTIVES

The proposed project has the following objectives:

6.1. Main objective

Assess the **maternal and foetal complications of non- and low-risk pregnant women who have an underwater delivery** compared to those who deliver on land, thus determining safety.

6.2. Secondary objectives

1. Analyse the **childbirth experience through the Childbirth Experience Questionnaire-E** of women who use a birth pool with respect to those who do not involve water in her childbirth process.
2. Compare the **rate of epidural analgesia requests** between women who labour in water versus those who labour on land.
3. Quantify the **number of prolonged labours** when women are labouring in water in comparison when they are not.
4. Determine **how many deliveries require obstetric intervention** when women have an underwater delivery versus when they deliver outside.

7. SUBJECTS AND METHODS

7.1. Study design

This project is designed as a **multicenter quasi-experimental study** to make a superiority comparison of safety between two strategies: **WB** versus **LB** in uncomplicated pregnancies, in favour of the former.

Participants will be able to choose where they give birth until the very last moment; therefore, the two groups will be created **without using randomization,** and therefore **non-equivalence** between them will be assumed. In one group there will be women who have chosen WB **(intervention group)** and the **control group** will be composed of women choosing LB.

There are several types of non-equivalent groups designs; the chosen one will be the **posttest only non-equivalent groups design,** in which only one measurement is made, after the intervention has come.

The study will be **multicenter** as it will be conducted at more than one hospital all over Catalunya.

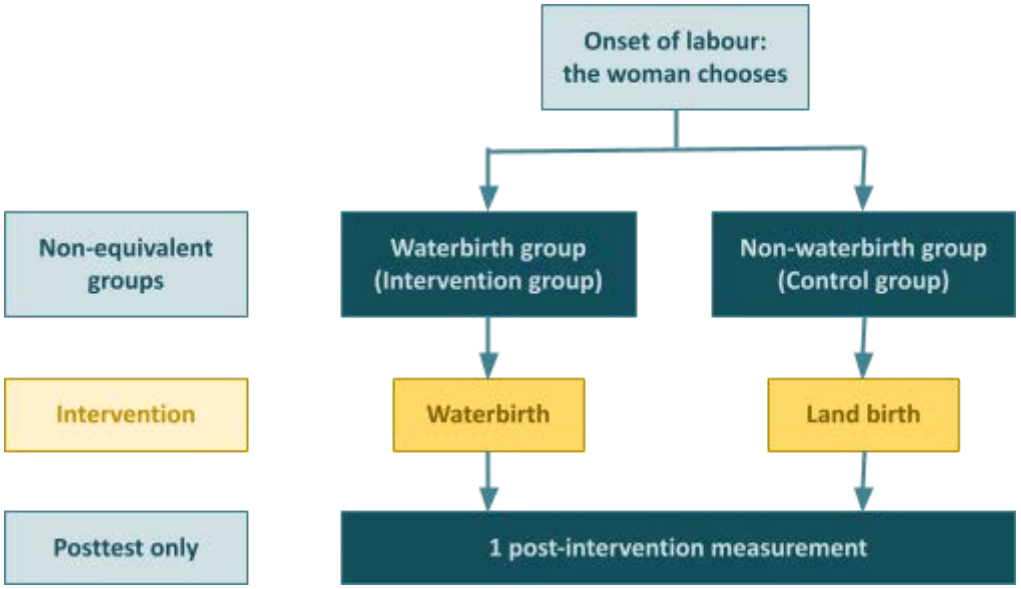

***Figure 9**: Outline of the study design.*

7.2. Study setting

The study will be carried out simultaneously in **8 hospitals of different health regions all over Catalunya: Hospital Germans Trias i Pujol, Hospital de Tortosa Verge de la Cinta (HTVC), Hospital Santa Caterina, Hospital de Palamós, Fundació Sanitària de Mollet (FSM), Hospital Universitari Josep Trueta (HUJT), Hospital General de Granollers and Hospital Clínic de Barcelona.**

These hospitals have been chosen because they offer a **public service** and because they all **currently offer the WI option,** according to the latest data collection on this topic, in 2022 (74). Although **not all of them contemplate an underwater birth in their protocol,** as in the case of HUJT, Hospital General de Granollers and Hospital Clínic de Barcelona, they all do have the necessary equipment to make it possible, and are working to implement the option in the near future.

The intervention takes place in the **natural childbirth room** of each hospital, which is understandably **different**; some have a ward annexed to the hospital that is run solely by midwives, while others share a delivery room with obstetrics and gynaecology (see ***Figure 10***).

Figure 10: *Natural delivery room in Hospital Verge de la Cinta (upper left), in Hospital Germans Trias (upper right), in Fundació Hospital Mollet (bottom left) and in Hospital Clínic de Barcelona (bottom right)* (78–81).

Nevertheless, they all have one thing in common: the natural childbirth room is a **unique space** for the mother where dozens of options for pain relief can be found and where **midwives**, the professionals who are responsible for non and low-risk pregnancies, accompany her throughout the process.

In addition, all participating hospitals have **direct or very close access, without long delays** (in the same hospital or a few km away)**, to these related specialisations** if need in an acute or emergency situation:

- **Obstetricians** if the labour or birth becomes complicated.
- **Anaesthetists** if epidural analgesia is requested.
- **Intensivist** if major complications affecting women's health appear, requiring admission to Intensive Care Unit (ICU).
- **Paediatrician** if some neonatal complications appear, requiring admissions to NICU.

Table 1: *Characteristics of hospitals included in the study: location, geographical area of care, basic population and offer in water immersion and/or waterbirth at the moment* (82–91).

WI: water immersion. WB: waterbirth.

Hospital	Location and geographical area of care	Basic population (inhabitants)	WI	WB
Centre de naixements 'Casa Laietània' Hospital Germans Trias i Pujol	Badalona (Barcelonès Nord, Maresme)	800.000	**Yes**	**Yes**
Hospital de Tortosa Verge de la Cinta	Tortosa (Terres de l'Ebre)	150.000	**Yes**	**Yes**
Hospital Santa Caterina	Salt (Gironès, Selva Interior)	147.000	**Yes**	**Yes**
Hospital de Palamós	Palamós (Baix Empordà)	130.000	**Yes**	**Yes**
Fundació Sanitària Mollet	Mollet (Vallès Oriental i Occidental)	150.000	**Yes**	**Yes**
Hospital Universitari Josep Trueta	Girona (Gironès, Pla de l'Estany)	800.000	**Yes**	**No**
Hospital General de Granollers	Granollers (Vallès Oriental)	400.000	**Yes**	**No**
Hospital Clínic de Barcelona	Barcelona (Barcelona Esquerra, Vallès Oriental, Osona)	540.000	**Yes**	**No**

7.3. Study population

Of interest, the **pregnancy risk** is assessed at the start of the pregnancy, at the first prenatal visit (10 WG); nevertheless, risk is a **dynamic condition** and **not a once-only measure**, as it can change over the course of the antepartum, intrapartum, and postpartum periods, even in an acute and unexpected form (25,26). At any moment early complications may become apparent and may induce the decision to refer the women to a higher level of care. For this reason, it will be continuously monitored throughout gestation and labour (25).

Very frequently women who meet a risk criterion at the beginning of pregnancy, such as a history of uterine cervical incompetence, are classified as 'high-risk pregnancy' because they are more likely to be affected again. However, at the end of pregnancy this condition can be confirmed (if passed), ruled out (if not passed) or overcomed (if it has happened but no longer exists). The reverse can also happen; a woman may be diagnosed with eclampsia at the end of her pregnancy, thus determining that she is at 'very high-risk', when she had always had a 'non-risk pregnancy', for example.

Hence, **the final risk calculated at the end of pregnancy is closer to the reality of childbirth**. In consequence, not to lose too many potential participants, **the first time the risk will be taken into account will be from the 35-36 WG visit**, close to the due date.

Therefore, there will be **2 moments of eligibility** in the study, with different criteria for each (see ***Figure 11***):

- **Eligibility 1:** it will be at the 35–36 WG visit in the third trimester. Pregnancy risk will be reassigned with respect to the risk established in subsequent visits, based on the information obtained from the anamnesis, the general physical and obstetric examination, as well as the complementary examinations (ultrasounds and laboratory tests indicated and the group B Streptococcus (GBS) culture). This way, women initially included will be **those considered 'non-risk' and 'low-risk' close to the due date** who have signed the informed consent (IC) (see ***ANNEX 3***), who are expected to arrive with the same risk at the time of delivery.

- **Eligibility 2:** posteriorly, at the time the mother self-presents to the hospital with concern for the onset of labour, and once confirmed that she **is into labour** and before entering the second stage, which can be at 37–41+6 WG, the risk will be reassigned following other eligibility criteria. The final women included will be those **who continue to belong to the 'non- or low-risk' group in terms of complications during childbirth.**

As done in other studies, for each variable examined, responses of "unknown/not stated" resulted in assignment to the 'high-risk group', to maintain a strict definition of 'non- or low risk'.

***Figure 11**: Moments of eligibility. WG: weeks of gestation.*

7.3.1. Inclusion criteria

GENERAL INCLUSION

- **Who is between 18 – 40 years old**
- **Who is able to speak and understand Catalan, Spanish and/or English**
- **Who has adequate level of awareness and ability to collaborate throughout the process**
- **Who has fulfilled continuous pregnancy care:** as a general rule, it is recommended women with straightforward pregnancy attend 9 prenatal visits according to 'Protocol de seguiment de l'embaràs a Catalunya' (27). During these visits and the preparation for the birth, the woman has received information from the professional and has been able to express her doubts, fears and preferences.
- **Who is interested in having a natural childbirth:** it includes many different ways of giving birth without using pain medication as epidural analgesia
- **Who has the ability to move easily**

INCLUSION 1

- **Who is at 'non- or low-risk' close to the due date,** according to ***Table 2***.
- **Who has an estimated normal foetal weight** (10 – 90th percentile for gestational age).

Table 2: *Criteria for 'Inclusion 1'. Adapted from 'Protocol de seguiment de l'embaràs de Catalunya'* (27)*, with variations designed to be more suitable for a third trimester.*

INCLUSION 1 (RISK CLOSE TO THE DUE DATE)	
NON-RISK	
• Not possible to demonstrate any of the risk factors that are systematically sought	
LOW-RISK	
• **Unwanted pregnancy** • **Inadequate vaccination status** • **Short intergeneric period** (<12 months) • **History of intrauterine growth retardation and low birth weight neonates** • **Previous sterility** • **Previous induction** • **History of placental pathology** • **History of obstetric pathology in previous pregnancies** • **Unfavourable socio-economic conditions** • **Victim of gender violence** • **First trimester metrorrhagia** • **Infection risk**	• **Risk of isoimmunization** • **Hereditary family history that may interfere with the normal course of pregnancy** • **Previous perinatal death** • **Threatened preterm labour** • **History of abortion** • **History of uterine cervical incompetence** • **Previous chromosomal abnormality** • **Previous ectopic pregnancy** • **Previous gestational trophoblastic malignancy** • **History of preterm birth** • **Tobacco habit** • **Multiparity** (≥4 births)

INCLUSION 2

- **Who is in spontaneous active labour:** it will be considered with the appearance of regular and painful uterine contractions each 3 minutes, every contraction has a minimum duration of 1 minute with an objective change in cervical dilation and/or effacement (16). To assess this information, vaginal examinations and CTGR will be used.
- **Who is predicted to have a 'non- or low-risk childbirth' and can have a vaginal birth:** meeting all these factors:
  - Gestational age of 37+0 to 41+6 WG, also defined as a term pregnancy
  - Cephalic presentation
  - Intact membranes. In case of spontaneous rupture of membranes, with evidence of clear amniotic fluid and for less than 24 h
  - Reactive foetal heart rate pattern seen in the CTGR

7.3.2. Exclusion criteria

EXCLUSION 1

- **Who is at 'medium-, high or very high-risk' close to the due date,** according to ***Table 3***.

Table 3*: Criteria for 'Exclusion 1'. Adapted from 'Protocol de seguiment de l'embaràs de Catalunya'* (27), *with variations designed to be more suitable for a third trimester.*
BMI: body mass index. WHO: World Health Organization. WG: weeks of gestation. Hb: haemoglobin. CBC: complete blood count.

EXCLUSION 1 (RISK CLOSE TO THE DUE DATE)	
MEDIUM RISK	
• **Pelvic abnormality** • **Low height** (<145 cm) • **Inadequate pregravid BMI** (<18.5 or >29) • **Cardiovascular risk WHO I** • **History of dystocic labour** • **Previous uterine surgery**	• **Previous caesarean** • **Mild preeclampsia** • **Personal antecedents of mental pathology** • **Current controlled and stable mental pathology** • **Well-controlled and diet-corrected gestational diabetes**
HIGH-RISK	
• **Morbid obesity** (>40) • **Severe pre-eclampsia** • **Endocrinopathies** • **Cardiovascular risk WHO III** • **Pre-pregnancy hypertension** (≥140/90mmHg) • **Twin pregnancy** • **Gestational diabetes corrected with diet and insulin**	• **Isoimmunisation Rh(D)** • **Current serious mental pathology** • **Severe anaemia** (Hb <9 g/dl and/or a CBC <25%) • **Suspected foetal malformation** • **Cardiovascular risk WHO II** • **Treatment with anticoagulants or coagulopathies** • **Maternal infection diagnosed during pregnancy** • **Oligohydramnios or polyhydramnios**
VERY HIGH-RISK	
• **Serious associated pathology** • **Type 1 or 2 diabetes** • **Cardiovascular risk WHO IV** • **Syndrome of dependence on alcohol and/or other drugs** • **Diagnosed uterine malformations that hinders the development of the pregnancy**	• **Multiple pregnancy** (≥3 foetus) • **Delayed intrauterine growth** • **Confirmed foetal malformation** • **Abnormal placental status** • **Eclampsia** • **Premature rupture of membranes** • **Previous uterine rupture**

EXCLUSION 2

- **Who presents a new contraindication for vaginal delivery:**
  - Clinical signs of maternal active infection: fever (>38ºC), tachycardia (>100/min), uterine fundal tenderness, purulent and foul vaginal discharge
  - Severe bleeding
  - Active genital herpes

7.3.3. Withdrawal criteria

- **Woman follow-up loss:** when it is not possible to contact the participant, when she stops coming to the pregnancy control visits, when she decides/has to give birth in a hospital that is not included on the list of "study setting" for whatever reason.
- **Request to revoke consent for the study:** the participant can express a voluntary decision to be excluded from the study at any point.
- **Woman's death:** from entry into the study to the day of the intervention.
- **Stillbirth:** including late stillbirth (between 28-36 WG) and term stillbirth (after 37 WG, but before delivery).

7.4. Sampling

7.4.1. Sample size

According to the largest retrospective cohort study published about births in water in the UK from 2021 (72), the incidence of complications in WB is known to be **small** as the table of results shows: only 3.53% had OASI, 0.89% PPH, 0,57% 5 minute low APGAR and 2.11% required neonatal admission.

Table 4: *Rates of complications among 46,088 women who had spontaneous vaginal delivery, from the study 'Waterbirth: a national retrospective cohort study of factors associated with its use among women in England'* (72).

	Number of women experiencing outcome (%)			Crude OR (95% CI)	Adjusted[a] OR (95% CI)	*p* value
	among all women (*n* = 46,088)	among women recorded as not having waterbirth (*n* = 39,824)	among women recorded as having waterbirth (*n* = 6284)			
Maternal						
Obstetric anal sphincter injury	1480 (3.21%)	1259 (3.16%)	221 (3.53%)	1.12 (0.97, 1.30)	1.00 (0.86, 1.16)	0.99
Postpartum haemorrhage >= 1500 ml	552 (1.20%)	496 (1.25%)	56 (0.89%)	0.72 (0.54, 0.94)	0.68 (0.51, 0.90)	0.007
Neonatal						
Apgar< 7 at 5 min of age	270 (0.59%)	234 (0.59%)	36 (0.57%)	0.98 (0.69, 1.39)	0.95 (0.66, 1.36)	0.78
Neonatal admission[b]	1287 (3.09%)	1168 (3.25%)	119 (2.11%)	0.64 (0.53, 0.78)	0.65 (0.53, 0.78)	< 0.001

In a two-sided test, with an alpha equal to 5%, an statistical power equal to 80% and assuming that it would be **very safe** and therefore the incidence of complications will be **small**, 349 pregnant women will be needed in each group. Assuming a 30% drop-out rate, it is finally estimated that a total of **454 pregnant women should form each group (a total of 908 women).**

Computations were carried out with Prof. Dr. Marc Saez' based on the 'pwr' package of the free statistical environment R (version 4.2.2).

The design tries to reflect what is likely to happen in the real-world setting; approximately **30% of participants are expected** not to finally have an underwater birth because:

1) **5%** of women who met 'Inclusion 1' **will be lost before onset of labour** because it is estimated they will not meet the criteria of 'Inclusion 2', as their risk will have increased.
2) In the group of women who have chosen WB, it is estimated that **40% will get out of the water** before getting to the second stage of labour regarding two main reasons: the need for epidural analgesia and administration of oxytocin because labour has stalled. Taking into account the total number of participants, this represents a loss of **20% of the total number of participants.**
3) **5%** are estimated to sign the withdrawal consent at any moment of the study.

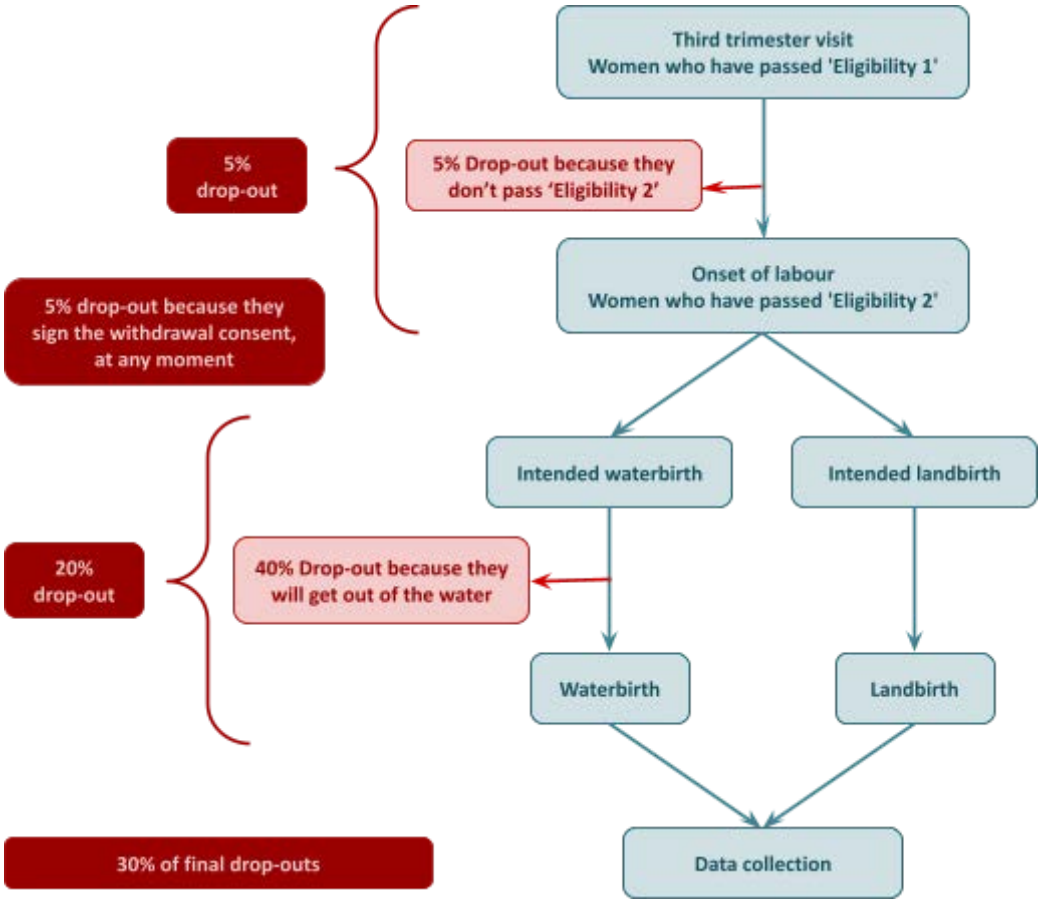

***Figure 12**: Drop-out estimation at each step of the study.*

As the sample is based on approximate data, once the information from approximately 20% of the women is obtained, the sample size needed will be recalculated based on the mean of proportion of these women for the main variable. In case a large sample is needed to obtain the minimum difference deserved, time recruitment will be extended.

7.4.2. Sample selection and recruitment time

The estimated time of recruitment will be **1.5 years.** Of the 8 hospitals:

- 3 of them, Casa Laietània, HTVC and Hospital Santa Caterina, have been offering WB for years, so there is a record of WBs attended each year.
- 1 of them, FSM, attends <500 deliveries per year but has had a birthing tub in the natural childbirth room for more than 3 years.
- Hospital de Palamós only introduced this practice last year, so there is still no data available.
- The other 3 hospitals do not yet contemplate expulsion, so it is difficult to estimate how many births they may have, although it should be noted that they attend a large number of births each year.

With all the WB data available, and knowing that **454 women are needed in each group**, it is estimated that 1.5 years would more than meet the number needed (see ***Table 5***).

During this period, the purpose of the project will be explained to all pregnant women who have a follow-up with the midwifery unit of those hospitals agreeing to participate in the study (see ***Study setting***). A **non-probabilistic consecutive method** of recruitment will be used in this study.

- From the first prenatal visit, when the woman is at 10 WG, she will be explained and provided with an **informative document** (see ***ANNEX 3***) regarding the study within the midwives' maternity education programme, and will be able to ask at each visit any questions or uncertainties she may have.
- On the 35-36 WG visit, those women who meet the inclusion criteria and none of the exclusion ones proposed will be asked to participate by being given the **IC document** (see ***ANNEX 4***). It's important that the physician highlights the voluntary and confidential aspects of their participation, as well as their right to withdraw from the study at any time.
- Once the woman accepts her participation in the study by **signing the IC,** they will be included in the sample. The process shall be **repeated** as many times as necessary to **obtain a sufficient number according to the calculated sample.** The time of recruitment is an estimation and as such it can be adjusted to the enrollment rates during the first months of the study.

***Table 5**: Hospitals participating in the study and characteristics: births attended/year, waterbirth attended/year and an estimation of waterbirths attended/1.5 years* (82–91).

HOSPITAL	BIRTHS ATTENDED / YEAR	WB / year	WB / 1.5 years
Centre de naixements 'Casa Laietània' Hospital Germans Trias i Pujol	Not available	288	432
Hospital de Tortosa Verge de la Cinta	1.000 - 2.999	40	60
Hospital Santa Caterina	1.000 - 2.999	70	105
Hospital de Palamós	Not available	Not available yet (open in September 2022)	
Fundació Sanitària Mollet	<500	Not available	
Hospital Universitari Josep Trueta	1.000 - 2.999	Currently not offered	
Hospital General de Granollers	1.000 - 2.999	Currently not offered	
Hospital Clínic de Barcelona	3.000 - 4.999	Currently not offered	
TOTAL		398 WB / year	597 WB / 1.5 years

7.5. Variables and measurements

7.5.1. Independent variable

The intervention for the study will be the mode of natural birth. It is conceived as a **dichotomous qualitative variable** and expressed as WB / LB:

- **Waterbirth (WB):** women will enter a birthing pool from the moment she goes into labour.
- **Landbirth (LB):** any form of natural childbirth that does not involve WI.

Although the study takes into account the entire childbirth to respond to the secondary objectives, **the main focus is on the 2nd stage of labour** also known as delivery.

7.5.2. Dependent variables

Main dependent variable

The main dependent variable is safety in the second stage of labour. To consider a practice 'safe', it has to be for all the individuals it encompasses; in this case, the mother and child, which is why the variables affecting each individual are clearly differentiated.

Presence of **maternal or neonatal complications developed and/or death for any of both**, related to each type of childbirth, will be studied. All of them are understood to be potentially serious, which may change the thinking of a woman who wants to give birth in the water. Each complication is a **dichotomous qualitative variable.** The outcome variable is a composite indicator also defined as a **dichotomous qualitative variable,** with values **'Safe'** if none of the listed complications are met, **'Unsafe'** if at least one unexpected adverse outcome appears.

MATERNAL COMPLICATIONS

1) **OASI** [Time Frame: 1 day]: includes **3rd and 4th degree perineal tears**, the most severe and causing the most morbidity, such as faecal or gas incontinence (see ***Disrupting the normal process***). Shall be answered "no" in the absence of tearing or in case of lower level tear.

2) **Early PPH** [Time Frame: 1 day]: by **gravimetric** or also called **visual quantification**, the professionals attending the birth will make an approximation of the average blood loss, considering the presence of early PPH a cumulative blood loss of greater than or equal to **1,000 mL** or blood loss accompanied by **signs or symptoms of hypovolemia within 24 hrs** after the birth process. They will be provided visual aids such as the one below.
   - **Signs of hypovolemia:** tachycardia, hypotension, oliguria
   - **Symptoms of hypovolemia:** dizziness, syncope

***Figure 13**: Tool for gravimetric estimation of early postpartum haemorrhage: a) gauze b) compress c) nappy* (92).

3) **Maternal peripartum infection** [Time Frame: 15 days]: it will be suspected with a **worsening of the woman's general condition** accompanied with **fever (>38ºC)**. It includes two diseases (see ***Disrupting the normal process***):
   - **Chorioamnionitis**: fever (>38ºC) plus one of a) maternal tachycardia, b) foetal tachycardia, c) uterine tenderness, or d) foul-smelling vaginal discharge during labour.
   - **Endometritis:** at least one of the following a) abdominal pain with no other recognised cause, b) uterine tenderness with no other recognised cause, or c) purulent drainage from the uterus.

   Subsequently confirmed by an elevated C-Reactive Protein (CRP) in blood tests and positive cultures of the samples collected.

4) **Shoulder dystocia** [Time Frame: 1 day]: difficulty in spontaneous emergence from the baby's shoulders requiring additional obstetric manoeuvres to produce foetal expulsion after head emergence, because maintained traction is not sufficient. It is considered an **obstetric emergency** with the added difficulty that the woman is in the water, where these manoeuvres become more than challenging (see ***Disrupting the normal process***).
   - **Signs to look out for:** difficulty in expulsion of the face and chin, retraction of the foetal head against the perineum (turtle sign) and absence of shoulder descent after moderate axial traction of the foetal head.

5) **Admission to the ICU** [Time frame: 10 days]: the indications for admitting a woman to the ICU are requiring advanced respiratory support, requiring support of two or more organ systems, women with chronic impairment of one or more organ systems who also require support for an acute reversible failure of another organ.

6) **Maternal death** [Time frame: 2 days]: women die as a result of major complications arising from childbirth.

NEONATAL COMPLICATIONS

1) **Umbilical cord avulsion** [Time Frame: 1 day]: total or partial rupture of the umbilical cord when bringing the newborn to the surface, before clamping the cord, resulting in blood loss.

2) **Birth trauma** [Time Frame: 1 day]: structural destruction or functional deterioration of the neonate's body due to a traumatic event at birth (93). It includes foetal laceration, fracture of the clavicle, humerus, or skull, brachial plexus injury, intracranial or subgaleal haemorrhage.

3) **Cardiopulmonary resuscitation (CPR) at delivery** [Time Frame: 1 day]: emergency medical intervention technique required in the first moments of birth because the baby is in a state of distress (example: asystolic, bradycardic, or pulseless electrical activity despite effective ventilation). It includes:
   - **Manual CPR:** 30 chest compressions followed by 2 rescue breaths.
   - **Use of automated external defibrillator (AED)**

4) **Low 5-minute APGAR score** [Time Frame: 1 day]: it is a screening tool to assess how the NB has reacted to previous care, remaining relevant for predicting neonatal survival (93). It comprises five components: colour, heart rate, reflexes, muscle tone and respiration, each of which is given a score of 0, 1, or 2 and are subsequently added together (94). Depending on the punctuation given to the NB, it is considered a 5-minute APGAR high score (≥7), meaning the NB is in good condition, or **low score (<7)** (see ***ANNEX 6***).

5) **Admission to a NICU** [Time Frame: 10 days]: patients admitted are those who are unstable and in need of intensive monitoring, potentially requiring immediate intervention in whatever moment. They may include patients with respiratory failure requiring ventilatory support, who are in shock or circulatory instability, need invasive monitoring and/or vasoactive drugs and/or acute haemodialysis.

6) **Respiratory distress** [Time Frame: 10 days]: to evaluate it objectively, the **Silverman test** (see ***ANNEX 7***) will be used, which takes into account 5 respiratory symptoms: thoracoabdominal movement dissociation, intercostal retraction, xiphoid retraction, nasal flaring and respiratory whining. Each of them is given a score of 0, 1 or 2 and are subsequently added together. It is considered the **newborn is in respiratory distress when the punctuation is >4**, and the answer "yes" shall be given.

7) **Early vertical sepsis** [Time Frame: 3 days]: infection occurring within the first 72h after birth as a consequence of colonisation by germs from the maternal genital tract. It will be suspected with clinical signs of sepsis (a worsening of the patient's general condition) and subsequently confirmed by an elevated CRP in blood tests, altered haemogram and positive blood culture.

8) **Early neonatal death** [Time Frame: 7 days]: falls under this variable data on:
   - **Stillbirth**: intrapartum death of a foetus known to be alive at the onset of labour.
   - **Early neonatal death:** death of a live born infant between 1 and 7 completed days of birth.

Secondary dependent variables

1) **Childbirth experience** [Time Frame: 6 weeks after the delivery]: the measuring instrument will be **CEQ-E**, the most recently published multidimensional instrument and the only one that comprehensively evaluates patients' perception and feelings (see ***ANNEX 8***). Even if CEQ was created for Swedish and nulliparous women, a recent study confirms that the CEQ-E can be considered a valid measure of women's perceptions of labour and birth in Spain, for both primiparous and multiparous women (95).

   This validated instrument is composed of **22 items** related to childbirth experience which are grouped into 4 domains: own capacity, professional support, perceived safety and participation. The response format is:
   - A 4-point Likert scale ranging from 1 (Totally agree), 2 (Mostly agree), 3 (Mostly disagree) to 4 (Totally disagree) for 19 statements. Negatively worded item scores are reversed.
   - A linear analog scale for the rest, in which scores are transformed to categorical values; 0–40 = 1, 41–60 = 2, 61–80 = 3 and 81–100 = 4.

   All item ratings are aggregated and then divided by the total number of questions, resulting in a **mean value**. This is a **continuous quantitative variable.** Higher overall scores on the CEQ-E represent more positive or preferable experiences (57).

2) **Epidural analgesia** [Time Frame: 1 day]: refers to local anaesthetics and adjuvants injected into the epidural space by lumbar puncture done by an anaesthetist. When the woman asks for pharmacological help to relieve pain and this medication is administered, the answer "yes" shall be given.

3) **Prolonged labour** [Time Frame: 1 day]: after entering the active phase of labour, no obstetric changes appear after **4 h in nulliparous** women and **3 h in multiparous** women.

   Subsequently, it requires the administration of oxytocin to augmentate labour (see ***Disrupting the normal process***). Answer "yes" shall be given if it occurs.

4) **Obstetric intervention** [Time Frame: 1 day]: it will be a **dichotomous nominal qualitative variable**, expressed with "yes" or "no" if at least one occurs (see ***Disrupting the normal process***):
   - **Episiotomy**
   - **Caesarean birth**
   - **Instrumental birth:** including the use of forceps or vacuum cup

__Table 6__: Summary table of independent and dependent variables.

ICU: Intensive Care Unit. NICU: Neonatal Intensive Care Unit. CPR: Cardiopulmonary resuscitation.

<table>
<tr><th></th><th>Variable</th><th>Type of data</th><th colspan="2">Categories or values</th></tr>
<tr><td>Independent variable</td><td>Mode of natural birth</td><td>Dichotomous nominal qualitative</td><td colspan="2">Waterbirth / Landbirth</td></tr>
<tr><td rowspan="15">Main dependent variable: SAFETY</td><td colspan="3">Maternal complications</td><td rowspan="15">Safe / Unsafe</td></tr>
<tr><td>Obstetric anal sphincter injury</td><td rowspan="6">Dichotomous nominal qualitative</td><td rowspan="6">Yes / No</td></tr>
<tr><td>Early postpartum haemorrhage</td></tr>
<tr><td>Maternal peripartum infection</td></tr>
<tr><td>Shoulder dystocia</td></tr>
<tr><td>Admission to ICU</td></tr>
<tr><td>Maternal death</td></tr>
<tr><td colspan="3">Neonatal complications</td></tr>
<tr><td>Umbilical cord avulsion</td><td rowspan="8">Dichotomous nominal qualitative</td><td rowspan="8">Yes / No</td></tr>
<tr><td>Birth trauma</td></tr>
<tr><td>CPR at delivery</td></tr>
<tr><td>Low 5-minute APGAR score</td></tr>
<tr><td>Admission to a NICU</td></tr>
<tr><td>Respiratory distress</td></tr>
<tr><td>Early vertical sepsis</td></tr>
<tr><td>Early neonatal death</td></tr>
<tr><td rowspan="4">Secondary dependent variables</td><td>Childbirth experience</td><td>Continuous quantitative</td><td colspan="2">Mean value of the punctuation</td></tr>
<tr><td>Epidural analgesia</td><td rowspan="3">Dichotomous nominal qualitative</td><td colspan="2" rowspan="3">Yes / No</td></tr>
<tr><td>Prolonged labour</td></tr>
<tr><td>Obstetric intervention</td></tr>
</table>

7.5.3. Covariables

There are other variables that could affect the dependent and independent variables, but they are not objects of study. As the following variables could act as confounders, control will be sought in order to increase the internal and external validity of the project.

MATERNAL DEMOGRAPHICS

- **Age**: it is a quantitative variable measured in years, but categorised in the following intervals, resulting in a **polytomous qualitative ordinal variable:**
  - 18-24 years
  - 25-29 years
  - 30-34 years
  - 35-40 years

- **Parity:** it will be treated like a **dichotomous qualitative variable divided into two categories:**
  - Nulliparous (0 previous births)
  - Multiparous (≥1 previous births)

- **Pre-gravid BMI:** BMI is calculated using the following formula BMI= Weight/Height2 and expressed in Kg/m2. This covariable will be registered using the BMI classification (96), considered as a **dichotomous qualitative ordinal variable:**
  - Normal weight: 18.5 - 24.9
  - Overweight: 25.0 - 29.9

- **Socioeconomic status (SES):** approximate with the combination of education level (**Polytomous qualitative ordinal variable**) and occupation (**Polytomous qualitative nominal variable**).
  - **Education level:** Without studies, Primary qualification, Secondary qualification, Diploma/Degree, Post-graduate
  - **Occupation:** Self-employed, Salaried worker, Pensioner, Student, Unemployed or looking for a job, Housewife, Other

- **Region of birth:** taking into account the most frequent origins residing in Catalonia, the following classification is presented. The variable is a **polytomous qualitative nominal** one.
  - Western Europe
  - Eastern Europe
  - Subsaharian
  - Other Africa
  - China
  - India/Pakistan
  - Other Asia
  - South and Central America
  - North America
  - Other

NB DEMOGRAPHICS

- **Birthweight:** once is born, the baby will be classified into one of these categories. It is a **polytomous qualitative ordinal variable:**
  - <2500 g
  - 2500 – 2999 g
  - 3000 – 3499 g
  - 3500 – 3999 g
  - >4000 g

- **Gestational age at delivery:** once is born, the baby will be classified into one of these categories. It is a **polytomous qualitative ordinal variable:**
  - Early term (37 – 38+6 WG)
  - Full term (39 – 40+6 WG)
  - Late term (41 – 41+6 WG)

INTRAPARTUM CHARACTERISTICS

- **Discontinuity of WI:** It will be a **dichotomous qualitative variable,** expressed with "**yes"** if a moment arrives when the midwife instructs the woman to get out of the water (see ***Safety***):
  - To avoid a potential complication
  - To treat a complication that is already present

Table 7: Summary table of covariables.

	Variable		Type of data	Categories or values
Covariables	**Maternal demographics**			
	Age		Polytomous qualitative ordinal	18-24 years / 25-29 years / 30-34 years / 35-40 years
	Parity		Dichotomous nominal qualitative	Nulliparous / Multiparous
	Pre-gravid body mass index		Polytomous qualitative ordinal	18.5 – 24.9 / 25.0 – 29.9
	Socioeconomic status	**Education level**	Polytomous qualitative ordinal	Without studies / Primary qualification / Secondary qualification / Diploma/Degree / Post-graduate
		Occupation	Polytomous qualitative nominal	Self-employed / Salaried worker / Pensioner / Student /Unemployed or looking for a job /Housewife / Other
	Origin		Polytomous qualitative nominal	Western Europe / Eastern Europe / Subsaharian / Other Africa / China / India / Pakistan / Other Asia / South and Central America / North America / Other
	NB demographics			
	Birthweight		Polytomous qualitative ordinal	<2500 g / 2500 – 2999 g / 3000 – 3499 g / 3500 – 3999 g / >4000 g
	Gestational age at delivery		Polytomous qualitative ordinal	Early term / Full term / Late term
	Intrapartum characteristics			
	Discontinuity of water immersion		Dichotomous nominal qualitative	Yes / No

7.6. Study intervention

7.6.1. Enrollment

It will be necessary that women included in study are at **'non- or low-risk' close to the due date** and **maintain these levels of risk for the moment of birth** (see ***Sample selection and recruitment time*** and ***Study population***).

7.6.2. Creation of the two groups

At the moment the woman enters the birth suite and is determined she is in active labour, **she will decide definitively whether to give birth in water or on land**, thus choosing to join the WBG or the non-waterbirth group (NWBG). From this point onwards, the intervention is initiated.

7.6.3. Intervention

A **midwife will be entirely dedicated to the labouring woman, with a 1:1 ratio.** This is because the intervention in both groups requires a lot of dedication and frequent monitoring that would be impossible to achieve with more patients under her care at the same time.

Foetal monitoring will be intermittent and done after a palpated contraction and at least every 5-15 minutes, depending on the stage, using window periods. The doppler ultrasound, the device to monitor the baby's heartbeat, will be wireless (and waterproof in the WBG) or, if wired, attempts shall be made to inhibit the woman's mobility as little as possible.

Waterbirth

There is no single right birth pool, but the **immersion receptacle** must have some crucial features: it has to be big enough to enable full mobility, flip over and adopt different positions with ease, thus achieving freedom of movement. It has to remain firm and stable to support women leaning against the sides, with enough water filled to submerge the woman's abdomen. The level of water should reach the woman's breasts when sitting, and has to be connected to a water supply (clean and hot running water).

***Figure 14**: Types of birth tubs or birth pools.*

Water has to meet specific **characteristics**: it will be only tap water, without additives on it. Although the ideal temperature is between 37-37.5°C, the woman herself can guide to find the most comfortable degrees. It is advisable to monitor the water temperature every 30 minutes in order to maintain it within its correct limits. The bath has to be filled with fresh water at the beginning of each delivery.

The **procedure** to be followed in this group is as follows:

- **First stage of labour:** the woman will enter the bathtub from the very beginning and will have one-to-one midwifery care, always counting on the presence of at least a water immersion-accredited midwife.
- **Second stage of labour:**
  - The midwife will support the woman's natural urge to push with a 'hands off' birth with quiet, supportive verbal guidance while awaiting for the spontaneous restitution and birth of the baby. Observation of the process may require the use of a mirror and a lantern underwater.
  - Of importance, it will be ensured **the baby is born completely underwater with no air contact.** That means once the foetal head is born it remains underwater until the body is born, when the baby is brought gently to the surface. If a woman raises herself out of the water at this point, exposing the foetal head to air, she should remain out of the water for the rest of the birth to avoid any risk of water inhalation if resubmerged.
  - In order to minimise the risk of avulsion, excessive cord traction will not be applied when the child is removed from the water. A check on the cord will be made.
  - Skin-to-skin contact between the newborn and mother will be maintained.

- **Third stage of labour:** once this point is reached, **she will exit the pool** and be transferred to a delivery bed (attached to the bath) for the placental birth. However, it will be tried not to interfere with the warm atmosphere that had been; maintaining ambient lighting and minimising distractions and stimulation.

Figure 15: *Casa Laietània Centre de Naixements, in the Hospital Germans Trias i Pujol (Badalona). Birth of Luca Castellanos Navarro, on 8 January 2022. Photographer: Adiva Koenigsberg* (97).

Landbirth

Includes any form of natural birth in which WI is not used. The woman acts in response to what she feels, using a wide variety of comfort measures to ease pain. These include: emotional support, relaxation techniques, a soothing atmosphere, listening to music, massages, taking a shower, aromatherapy, acupressure, placing a heating pad or ice pack on the back or stomach… She can also use some materials, like **steps, a birthing ball, liana, bar, bed or chair.**

The positions she can adopt are infinite, and will be to her preference: sitting, standing, stretching, on the chair, on all fours, on the bed, on the floor...

In conclusion, she is able to create an environment that is just what she needs as she does the hard work of labour and birth.

***Figure 16**: Labour and birthing positions for natural childbirth* (98).

7.6.4. Follow-up

After the day of delivery, when the intervention takes place, the woman will be followed for **6 weeks**, concluding in the postpartum closing visit with the midwife. During these 6 weeks, the variables will be collected in the **clinical history** of the woman and the baby respectively, as is done in normal practice, because they are all clinical reporting that is recorded by the professionals who attend the birth and follow the mother and the newborn in the subsequent visits.

The last variable to be collected will be the maternal survey on the birth experience (CEQ-E, see ***Annex 8***), at the aforementioned visit, which is the only one that deviates from standard practice.

After that, all the information will be available for the person in charge to fill in the eCRF for each participant.

7.7. Flow diagram

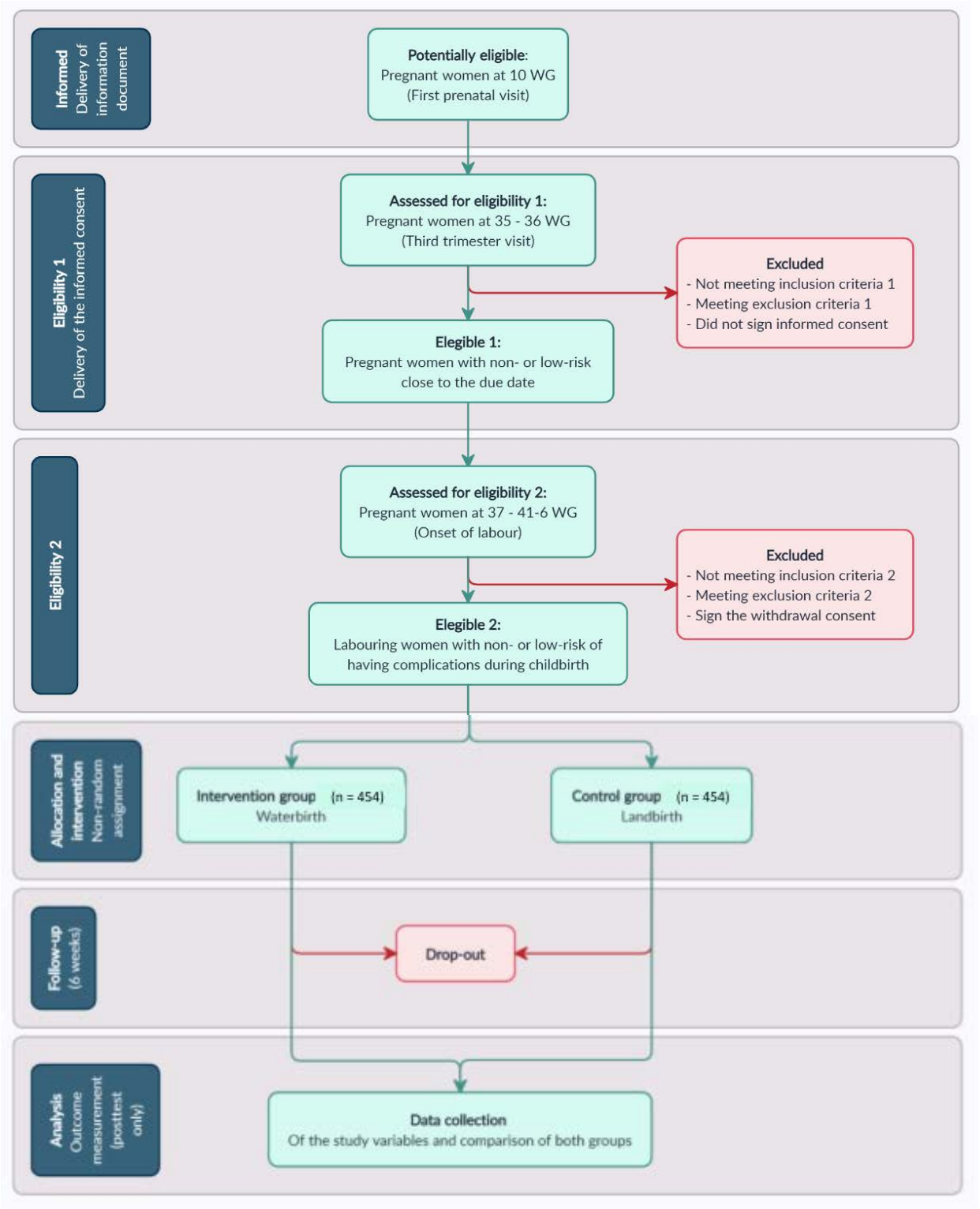

***Figure 17**: Flow diagram of the quasi-experimental study. WG: weeks of gestation.*

7.8. Data collection

Creation of the eCRF

All the information will be registered on an **electronic case report form (eCRF)** whether or not the woman has chosen to include water in her childbirth experience. The one selected is REDCap (***https://www.project-redcap.org/***), a secure web application for building and managing online surveys and databases, and a **computer scientist** (Comput. Sci) will be hired to create it.

eCRF fill out

All variables have a time frame ranging from 1 to 15 days, and the information shall be collected from the medical records of the mother and the child, respectively: maternal and neonatal complications, epidural analgesia, prolonged labour and obstetric intervention. In addition, all covariates will be collected as well.

There is only one variable that will be obtained a little later: it is the childbirth experience, which will be obtained at the last postpartum closure visit with the midwife, which is 6 weeks after the delivery. The CEQ-E will be passed to her on paper before entering the visit, while she sits in the waiting room.

Every **hospital coordinator (HC)**, the one in charge of collecting the data concerning his/her hospital, will be trained in the use of eCRF in order to avoid mistakes. To facilitate the process, data on the eCRF will be entered once the intervention has been completed and all data has been obtained **(post-intervention data collection).** In this, all women's personal and clinical information collected in this study will be anonymous and confidential because they will be identified through a **randomised code**.

Creation of the database and posterior analysis

Once every eCRF of every woman is collected, a **computer scientist** will create the **database** to gather all the data, always maintaining anonymity. The elaboration of a database will be fundamental in order to facilitate the subsequent data analysis.

Later on, it will be sended to the **statistician (stat)** to analyse.

***Figure 18**: Summary of the data collection. eCRF: electronic Case Report Form. HC: Hospital Coordinator.*

7.9. Safety

Rigorous protocols for candidate selection

To ensure that the woman who arrives in natural childbirth has the minimum chance of having a complicated delivery, **two moments of eligibility** have been specified in this study (see ***Study population***).

Infection precautions

It is foreseen that each hospital will receive a **training programme on pool maintenance and cleaning**, to avoid the onset of water-vehiculated infections for mothers and babies. A fixed pool should be disinfected as part of routine room cleaning. The pool shall be filled with clean, new water at the commencement of every labour and during the second stage of labour, any faecal matter that may appear should be removed with the aid of a strainer.

Possible WI discontinuity: emergency plan

Choosing to give birth naturally through WI does not mean that interventions will not be needed or that complications will not occur. Women who started WI at onset of labour may or may not give birth in the water; **the possibility of suspending WI if unexpected complications arise during labour should be discussed** with the pregnant woman beforehand as part of the information **prior to signing the IC** (see ***Annex 4***).

Criteria for leaving the bath

- Suspicious or pathological CTGR, that informs of loss of foetal wellbeing (see ***Table 8***)
- Excessive intrapartum haemorrhage
- Meconium amniotic fluid
- Prolonged labour (reduced and/or ineffective contractions) requiring administration of oxytocin*
- Alteration of maternal vital signs (hyperthermia, hypo/hypertension…)
- Signs of infection (fever, maternal/foetal tachycardia…)
- Request from the pregnant woman for epidural analgesia*
- Heavy contamination of the pool water, in order to clean or change the water
- Presence of shoulder dystocia requiring emergency manoeuvres

*They will be considered drop-outs.

***Table 8**: Cardiotocographic register: classification criteria, interpretation and recommended management* (99).

bpm: beats per minute.

	Normal	Suspicious	Pathological
Baseline	110-160 bpm	Lacking at least one characteristic of normality, but with no pathological features	< 100 bpm
Variability	5-25 bpm		Reduced variability for > 50 min, increased variability for >30 min, or sinusoidal pattern for > 30 min
Decelerations	No repetitive* decelerations		Repetitive* late or prolonged decelerations during > 30 min or 20 min if reduced variability, or one prolonged deceleration with > 5 min
Interpretation	Fetus with no hypoxia/acidosis	Fetus with a low probability of having hypoxia/acidosis	Fetus with a high probability of having hypoxia/acidosis
Clinical Management	No intervention necessary to improve fetal oxygenation state	Action to correct reversible causes if identified, close monitoring or additional methods to evaluate fetal oxygenation (chapter 4).	Immediate action to correct reversible causes, additional methods to evaluate fetal oxygenation (chapter 4), or if this is not possible expedite delivery. In acute situations (cord prolapse, uterine rupture or placental abruption) immediate delivery should be accomplished.

The moment of leaving

The path from the pool to the bed should be clear; there should be no electrical cords, equipment or wet floors, as spillages should be wiped up quickly. In case of emergency, nursing staff and orderlies will additionally assist the woman out of the bath to facilitate rapid transfer back to the woman's bed for care/monitoring.

Warm blankets and towels should be available at all times for the mother and baby, just as there should be no hesitation in making a call for help to other specialties if indicated.

***Figure 19**: Graphical representation of an emergency evacuation of the swimming pool (100).*

Safety is not a loss in the study

The fact that a percentage of women who are part of the WBG end up giving birth on land because of the appearance of complications is reassuring rather than worrying, and is not considered a loss in this study. The professionals attending the birth will be trained to **recognise potential complications** and thus **instruct the discontinuation of WI**. Therefore, leaving the pool in the second stage of labour on clinical indication is part of the safety of the WB intervention.

8. STATISTICAL ANALYSIS

The analysis of the data obtained will be done by a **statistical analyst**, who will do the investigation blinded to ensure he/she does not know which is the WBG, the one which has been intervened, and which is the NWBG, the one representing the control group. This way it will not interfere with the final result.

The software used will be *Statistical Package for Social Sciences (SPSS)* software version 28.1. A p-value of <0.05 will be considered statistically significant, defining a 95% confidence interval for all analyses.

8.1. Descriptive analysis

In both groups (WB and LB), the stat will summarise the **quantitative variable** (childbirth experience) by using **means, standard deviation, medians and interquartile range (IQR)**. **Qualitative variables** (safety in the second stage of labour, epidural analgesia, prolonged labour, obstetric intervention) will be described using **means of proportions.**

These descriptives will be stratified between WB and LB, and additional stratification will be done by the covariates.

8.2. Bivariate analysis

Student's t test will be used to study if there are differences depending on mode of birth with **quantitative variables** (means of childbirth experience).

Chi-square or Fisher's exact test (if the expected number of cases in a cell will be lower than 5) will be used for the difference of proportions of the **qualitative variables** (safety in the second stage of labour, epidural analgesia, prolonged labour, obstetric intervention) between the two groups (WB and LB).

8.3. Multivariate analysis

It will be necessary to do a multivariate analysis adjusting the independent variable with the dependent variables according to the covariates that can interfere in the results to avoid possible confusion.

A **linear regression** model will be used for the association of the intervention with **quantitative variables** (childbirth experience) and **multivariate logistic regressions** for the association of the intervention with the **qualitative variables** (safety in the second stage of labour, epidural analgesia, prolonged labour, obstetric intervention).

9. ETHICAL AND LEGAL CONSIDERATIONS

Ethical principles

The study will be performed under the requirements established by the World Medical Association (WMA) in the **Declaration of Helsinki** of Ethical Principles for Medical Research Involving Human Subjects (last revision in the 64th General Assembly, Fortaleza, Brazil, in October 2013). This quasi-experimental study obeys the **Principles of Biomedical Ethics from Beauchamp and Childress**, more commonly known as the four fundamental ethical principles:

- **Beneficence:** it is the moral obligation to act for the benefit of others. In this study this principle is fulfilled because all women will be attended by health care practitioners who are expected to **follow evidence-based practices** proven to be beneficial in supporting the normal physiology of labour and delivery. Moreover, the mode of birth implemented as an option for those women wanting to envelop water in her childbirth is **expected to be safer** than the conventional one, and with a **better childbirth experience.**
- **Non-maleficence:** no malicious intent is being done to the study participants. Evidence has been proving WI during labour has **no detrimental effects on maternal or neonatal outcomes**. The few known complications regarding WB involve the child who is about to be born exclusively.

  To warrant that this principle is complied for both of them, trained professionals will **assess the procedure risk twice to ensure it is and maintain to be low / non-existent**; on the third trimester and on the onset of labour. Only those resulting from the two moments of eligibility will be retained. In addition, the appropriate utilisation of procedures, risk screening, and expertise of the midwives make them capable of **recognizing potential complications** in the two groups, which will lead to the discontinuation of WI or to the call for other specialities as required.
- **Justice:** an **equitable distribution** of health resources will be respected in the study, and any **discrimination** to any group of women for care **will be avoided** to guarantee the principle of justice.

  All pregnant women attending the included hospitals who meet the inclusion criteria and do not have any exclusion criteria will have the **same possibility to enter in the study**. From those, everyone will be informed of the option to give birth in water or on land at prenatal visits and the moment of birth.

- **Autonomy:** it means recognising women's capacity to make certain choices about actions related to them, based on their values and preferences.

An **informative document** about the study protocol (see ***ANNEX 3***) in an understandable language for the possible participant will be given to provide the knowledge and understanding they need from the onset of pregnancy. **Written IC** (see ***ANNEX 4***) must be obtained by investigators from each participant before taking part in the study, on the third trimester of pregnancy, assuring that they understand what it entails, are free to refuse entry and can withdraw whenever they wish without prejudice. In consequence, the decision whether or not to participate in the study will be respected as it indicates ***Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica*** (44).

In addition, the study is designed in such a way that it **respects** at all times **where and how the woman wants to give birth** (see ***Study design***). Pregnancy is seen as a physiological state, and thus **over-medicalization is refused** to avoid the loss of women's control. If intervention is required, it should always be **informed and reasoned** so that the woman can understand it and also express her opinion, thus complying with the principle of autonomy.

Privacy and confidentiality

The confidentiality and privacy of the patient is guaranteed through ***Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales*** (101) and ***Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data*** (102). All women's personal and clinical information collected in this study will be anonymous and confidential because they will be identified through a **randomised code** in the eCRF and consequently in the database. Moreover, all the data collected will **only be available for the research team** exclusively used for the purpose of the research.

Comitè d'Ètica d'Investigació Clínica (CEIC)

The present project will be submitted to the **CEIC** from HUJT and posteriorly to the CEICs of all the other centres involved, and suggestions given will be considered and its approval will be compulsory before starting the study. The system of checks to be carried out during the course of the research shall be in accordance with the **Ley 14/2007, de 3 de julio, de Investigación biomédica** (103).

Transparency

Investigators of this study declare there are no conflicts of interest; the main goal of this research is to develop generalizable knowledge to improve human health and quality of life. Investigators agree to publish all data and results with total transparency including unfavourable data or events.

10. WORK PLAN AND CHRONOGRAM

10.1. Participating centres

The 8 centres proposed to carry out the study are as follows: Hospital Germans Trias i Pujol, Hospital de Tortosa Verge de la Cinta, Hospital Santa Caterina, Hospital de Palamós, Fundació Sanitària de Mollet, Hospital Universitari Josep Trueta, Hospital General de Granollers and Hospital Clínic de Barcelona.

10.2. Research team members

The personnel essential in the different stages of the quasi-randomised study include:

- **Main investigator (MI)**: is the person leading the study, who is in contact with the coordinators of each hospital and makes sure that everything goes as it should.
- **Hospital coordinators (HC):** in all the hospitals there will be a coordinator who collects the data and ensures that the whole procedure is being done in the correct way in his/her centre.
- **Health care professionals (HCP):** includes the midwives and nurses from each hospital who inform women in the prenatal visits, carry out the intervention and receive them once they are in the postpartum period.
- **Other staff:** nurses, statistician, computer scientist, cleaning staff, olderlies, training personnel, may include paediatricians, anaesthesiologists, obstetricians...

10.3. Study stages

The whole study will have an estimated duration of **42 months**, which is the same as **3.5 years.** The steps done on this quasi-experimental trial will succeed according the following order, grouped in **6 stages** each consisting of different activities:

STAGE 1: Elaboration of the protocol and study design (4 months: November 2022 – February 2023)

1. **First session** (November 2022, completed): in order to think about this project and what gaps of information there were in this area of study.
2. **Bibliographic research and protocol elaboration** (November - January 2022, completed): an extensive bibliographic research has been done to soak up the latest evidence on WB practice, as well as the redaction of the protocol.
3. **Hospitals participating contact** (February 2023): the MI will propose to the hospitals selected in the study to participate in it.
4. **Creation of the eCRF** (February 2023): a computer scientist will be hired with the aim of creating this way of collecting data.

STAGE 2: Ethical approval (3 months: February – April 2023)

5. **Ethical evaluation and approval:** the MI will present the protocol to CEIC of HUJT and subsequently, to the CEICs of all the centres participating in the study for its ethical approval. Any suggestions will be considered and consequently modified.

STAGE 3: Coordination and health professionals training (2 months: May – June 2023)

6. **Meeting in every hospital** (May 2023): the MI will meet the research team of each hospital included in the study and the decision of who will be the HC of which will be made.
7. **Formation sessions** (May - June 2023): the training of all the members who have a role in study is essential: 10 midwives from each hospital will attend a course called 'Parto en el agua' given by Barbara Harper, a professional will dedicate 1 h of training on cleaning and disinfection to each hospital and the selected HCs will also receive training on the use of eCRF. Everything they need to know about the study will be explained.

STAGE 4: Sample recruitment, intervention, and data collection (23 months: July 2023 – May 2025)

8. **Sample recruitment**: women will be recruited by a non-probabilistic consecutive method for this study. They will have to meet all the inclusion and none of the exclusion criteria, as well as sign the IC. The recruitment will last until each group is formed of 454 pregnant women, which is believed to take up to 18 months (July 2023 – December 2024).
9. **Intervention:** as the pregnant women reach the time of delivery, the intervention, which is the mode of natural birth, will take place. Depending on their decision, they will enter either the intervention group (WB) or the control group (LB).
10. **Follow-up:** once the intervention has taken place, up to 6 weeks after the delivery, the HCP will collect the variables, as all clinical data are recorded in the medical records of the mother and baby.
11. **Post-intervention data collection:** all the information necessary to fill in the eCRF will be collected, done by the HC of each hospital.

The sample recruitment will take place in parallel with activities 9 and 10. When the woman enters the study (35 – 36 WG), it may take between 1 and 7 weeks for her to go into labour and for her childbirth to be at term (37 – 41+6 WG). Once the intervention has occurred, a follow-up of 6 weeks will be done for each participant.

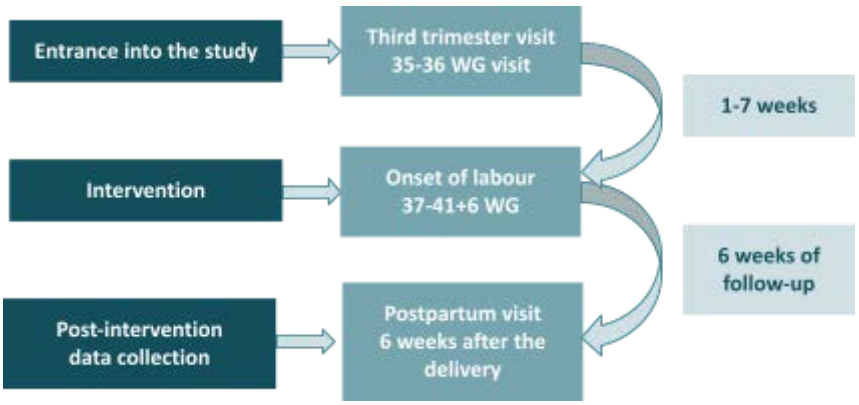

Figure 20: *Total time of participation of each woman. WG: weeks of gestation.*

STAGE 5: Data analysis and interpretation (4 months: June 2025 – September 2025)

12. **Creation of the database** (June 2025): a computer scientist will be hired to create a database with all the anonymous data recollected in the eCRF of each participant.
13. **Statistical analysis** (July – August 2025): performed by a statistician, who will analyse all the data collected through a descriptive, bivariate and multivariate analysis. Posteriorly, he/she will interpret the data obtained.
14. **Results and conclusions** (September 2025): the statistician will present the results to the whole research team, who will discuss the outcomes and draw conclusions.

STAGE 6: Results publication and dissemination (7 months: October 2025 – April 2026)

15. **Article writing, revision and publication** (October 2025 – January 2026): the MI will write the final article with the results and conclusions. It will be edited and supervised by English correctors and published afterwards.
16. **Dissemination** (February – April 2026): the written study will be published as a journal article and the article will be presented to the SEGO and AEP. National and international congresses will be attended to present the results.

10.4. Chronogram

STAGES AND ACTIVITIES	STAFF	YEARS																																							
		2022		2023												2024												2025												2026			
		N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A
STAGE 1 – ELABORATION OF THE PROTOCOL AND STUDY DESIGN																																											
1. First session																																											
2. Bibliographic research and protocol elaboration	MI																																										
3. Hospital participating contact																																											
4. Creation of the eCRF	Comput. Sci																																										
STAGE 2 – ETHICAL APPROVAL																																											
5. Ethical evaluation and approval	CEIC																																										
STAGE 3 – COORDINATION AND HEALTH PROFESSIONALS TRAINING																																											
6. Meeting in every hospital	MI, HC, HCP																																										
7. Formation sessions																																											
STAGE 4 – SAMPLE RECRUITMENT, INTERVENTION AND DATA COLLECTION																																											
8. Sample recruitment																																											
9. Intervention	HCP																																										
10. Follow-up																																											
11. Post-intervention data collection	HC																																										
STAGE 5 – DATA ANALYSIS AND INTERPRETATION																																											
12. Creation of the database	Comput. Sci																																										
13. Statistical analysis	Stat.																																										
14. Results and conclusions	MI, HC																																										
STAGE 6 – RESULTS PUBLICATION AND DISSEMINATION																																											
15. Article writing, revision and publication	MI																																										
16. Dissemination																																											

11. BUDGET

11.1. Not-included costs

- **Staff:** the personnel participating in the research team will not be extra rewarded for this reason. It is considered that their motivations for joining the study should not be incentivized for any economic grounds, because researchers are rewarded by the scientific prestige and intellectual gains. They are: MI, HC, midwives (HCP), obstetricians, paediatricians, anaesthesiologists, nurses, orderlies and cleaning staff.
- **Available materials**: the hospitals chosen already dispose of the materials for the care of normal childbirth, both WB and LB, so this material will not be considered in the study budget. It includes:
    - WI and WB: bath or birth pool, access ladder to the bath, waterproof Doopler, handheld mirror, aquatic lantern, water thermometer, strainer (to remove faecal contamination), waterproof apron, towels and special length gloves.
    - LB: CTGR, birth ball, low stool, non-slip mat, cushions, kneeler pads, cords, hammock…

11.2. Included costs

Personal costs

- **Training session on data collection with eCRF:** a course is planned for all HCs to learn how to use the eCRF. The person imparting the training course will be paid 35€/h, and he/she will perform a 10-hour course.
- **Midwifery education:** all midwives attending WBs will receive a course for professionals called "El parto en el agua", given by Barbara Harper. It consists of a 16-hour course and the price is 350€ per person. An average of 10 positions will be offered to each hospital, and there are 8 hospitals participating in the study.
- **Training programs of cleaning procedures**: to increase the right knowledge of the cleaning operators and thus avoiding the onset of water-vehiculated infections, a training program will be offered in each hospital. The person imparting the training course will be paid 40€/h, and will give 1 talk of 1 hour in each hospital.

Subcontracted services

- **Statistical analysis:** the subcontracted statistical analysis service, made by an statistician, will be paid 35€/h, with an estimated total of 150h of work.
- **Creation of eCRF and database**: although eCRF will be created with REDCap (a free registration page), a computer scientist will be hired to create this eCRF and the shared database. This service is budgeted 30€/h, with an estimated total of 100h of work.

Material costs

- **Printing costs:** informative document (5 pages), informed consent (1 page) and CEQ-E (6 pages) are required to be printed for each subject. That total is approximately 15 pages per woman. The printing cost is 0,03€/page. An estimated sample size of 908 participants is needed. However, it is possible that more information documents may need to be printed, as required by the centre.

Travel expenses, allowances and meals costs

- **Hospital coordinators meetings**: during the study, the MI, all HCs and some other specialists (statistician, the training person) will meet a total of 4 times. It is budgeted 100€ to cover travel, allowances and meal costs per person, per meeting.

Divulgation costs

- **Publication fees**: it is expected to publish a journal article exposing the main results. It is assumed 1,500€ for publication fees.
- **Linguistic correction:** before submitting the article to the journal, the work of a linguistic proofreader will be required to avoid errors. It is budgeted 300€ for his/her services.
- **National and international congress:** to disseminate the results, the MI will present the study results at a national and international congress, with 750€ and 2,000€ per inscription respectively. In addition, the travel, accommodation and diets will be also included (250€ and 500€ extra).

To try to cover as many expenses as possible, this protocol will be submitted to **multiple public and private funding calls.** One example will be 'Beca Nacional per a la Recerca Clínica', from the Dexeus Foundation, a grant aimed at young researchers, graduates and postgraduates in health sciences, to finance their research projects in the fields of: General Gynaecology, Maternal-Fetal Medicine, Oncological Gynaecology, Reproductive Medicine and Basic Research in the field of Obstetrics and Gynaecology.

***Table 9**: Budget details of the study.*

eCRF: electronic Case Report Form. IC: informed consent.

CEQ-E: Childbirth Experience Questionnaire Spanish version.

	TYPE OF COST	UNIT COST	HOURS OR UNITS	SUBTOTAL
Personal costs	**Training session on data collection with eCRF**	35€ / h	10 h	350€
	Midwifery education	350€ / midwife	10 midwives x 8 hospitals	28,000€
	Training programs of cleaning procedures	40€ / h	8 h	320€
				Subtotal: 28,670€
Subcontracted services	**Statistical analysis**	35€ / h	150 h	5,250€
	Creation of eCRF and database	30€ / h	100 h	3,000€
				Subtotal: 8,250€
Material costs	**Printing costs** (informative document, IC, CEQ-E)	0,03€ / page	12 pages x 908 participants	326.88€
				Subtotal: 326.88€
Travel expenses, allowances and meals costs	**Hospital coordinators meetings**	100€ / attendant	4 meetings x 8 head researchers	3,200€
				Subtotal: 3,200€
Divulgation costs	**Article publication fees**	1,500€ / publication	1	1,500€
	Linguistic correction	300€ / article	1	300€
	National congress	1,000€ / per attendant	1	1,000€
	International congress	2,500€ / per attendant	1	2,500€
				Subtotal: 5,300€
			TOTAL COST	**45,746.88€**

12. LIMITATIONS AND STRENGTHS

Limitations

The greatest disadvantage of the **quasi-experimental design** is that randomization is not used when creating the two groups, **limiting the study's ability to conclude a causal association** between an intervention and an outcome. As the groups are non-equivalent, and the sampling method is a consecutive non-probabilistic one, it is possible to encounter a **selection bias**, when a sample does not resemble the reality of the population, obtaining unrepresentative results. However, these problems will be minimised in the multivariate analysis, when the effects of potential confounding factors will be adjusted, and thus interval validity of the study will increase.

When talking about **safety**, there is something to comment. It is a term that probably has shades of grey, and is not just black and white. So much so that when thinking generally about safety, it may occur to us that an intervention can be 'very safe', 'quite safe', 'fairly safe', 'slightly safe' and 'unsafe'. However, there is no study in the present literature regarding this theme that represents safety as a qualitative ordinal polytomous variable. In the end, everyone is talking about childbirth, an unforgettable and perhaps the most important moment in the life of the future NB. It would not be fair to make the woman choose between so many levels and besides, it might be useless; anything that was not classified as 'very safe' for her and her baby would not be considered as a feasible option, and would immediately be ruled out. Therefore, informing her whether a practice is 'safe' or 'unsafe', as a **dichotomous variable,** seems a better option.

In this study, a **high loss rate is estimated (30%),** particularly at the time of intervention, in the WB group. Although all participants confirm that they are interested in natural childbirth, not all of them are finally able to cope with the pain without the help of epidural analgesia. There are many methods to manage pain during labour, but for some women they may not be sufficient. Some **women who had not planned to receive pain medication change their minds when they are going through labour**; this is common and completely understandable. This is why it is estimated that approximately 4 out of 10 women will eventually opt for the pharmacological method, which will force them out of the water, and represent a loss of the group. The same will happen with prolonged labour, although to a lesser extent. To deal with this limitation, this has been taken into account when calculating the sample size.

With regard to the **eligibility criteria,** responses of "unknown" or "not stated" when talking of the listed characteristics of every risk group were assigned to the 'high-risk' group. This likely resulted in misclassification, because the probability of being high risk for any individual characteristic was low. Therefore, priority is being given to **the 'non or low-risk' group to be truly low risk,** at the expense of possibly including some low-risk women in the high-risk group. However, it is not expected that the possible misclassification would differ the results.

Moreover, in this protocoled study only straightforward pregnancies were the ones included to participate, potentially **limiting the generalizability of the results to all other pregnant women.** This was done this way because there is so much controversy, the preference is to start with demonstrating that WB is a safe option for women and babies without risk and, in future studies, to lower the strict inclusion criteria and be able to represent a larger part of the population.

Being a **multicenter study**, in which the **intervention is dependent on the professional** attending the labouring woman, there is a chance of **inter and intra variability** not only between hospitals but also between professionals from the same hospital.

- Performing intervention. Not all hospitals have the same years of experience with WB.
- Evaluations of the variables included in this study, causing an information bias. One example could be 'early PPH', where it is hard to calculate the amount of blood lost through bloody compresses.

To avoid this possible variability, **training** of professionals in intervention is envisaged, and the variables are **well defined** with the help of drawings and scales to reach unanimity.

Strengths

WB is a **new and growing issue,** and the study has an **achievable budget**.

The **degree of evidence** in a quasi-experimental study is higher than in an observational study, from which most of the complications reported in the literature originate.

Recording data in an **eCRF** is believed to be the most suitable way of data collection. It offers time optimisation (data entry is faster than in paper format and it is already directly into the database for the analysis), lower failure rate (it can detect incorrectly entered data) and systematically inserted information (as the study is conducted at different centres, data can be inserted from each site, making it immediately available to data reviewers).

13. CLINICAL AND HEALTHCARE IMPACT

Childbirth is a first-hand experience for half of the population. The **interest in natural childbirth continues to grow**; more and more women are deciding to live this overwhelming experience without the help of drugs or medical interventions, having the feeling that they are the ones who take control. How women experience this process is more than relevant, and any change for the better will always have a great impact. Therefore, when WB is offered to low-risk women with the same ease that conventional birth is offered, change will begin.

First of all, the analgesic effect of water will help women **endure pain without medication**, and **adverse effects** arising from this, such as decreased blood pressure, headache, immobility and urine leakage, will be **less frequent** among women who have given birth.

Secondly, it will be necessary to redistribute the workload among professionals, **enhancing the role of midwives**, who will have to receive **specialised formation** in this type of delivery. This will inevitably lead to **less medicalised deliveries** and **fewer caesarean sections** and, consequently, to a **better distribution of human and material resources.**

In the third place, medical support regarding WB will represent a **change in attitude from the public towards this type of more physiological births**, seeing it as a healthy and safe option, among others, and equally safeguarded. This way, the woman who aspires to have a natural birth will not only be **supported** by her medical team, but also by her **partner, friends and family.**

Lastly, when all catalan hospitals have birthing baths and trained professionals to impart it, **Catalunya will become a reference model** for initiating a change in maternity and childbirth care. A **space for sharing cases, doubts and criteria for action** will be created and a **common action protocol** for all the ACs will ensure that the health system guarantees the right of women to freely choose the place where they give birth in a homogeneous way.

Demonstrating that WB is a safe option is the missing point for important associations such as SEGO and AEP, who are committed to defending the Spanish model of OB-GYN and paediatric care, to overcome the fear of the new and accept that sometimes change is for the better. It is therefore necessary to escape from preconceived ideas and prejudices, and to accompany women in making truly informed decisions, enhancing their autonomy about birthplace options.

14. FEASIBILITY

This multicenter quasi-experimental study will be carried out in 8 hospitals, the vast majority of whom have been **experienced in WI as a technique of pain relief for many years**. With the participation of all these centres, it is feasible to **achieve the required sample size** (908 patients) in 1.5 years, which is **not** considered to be **a very long period.**

WB is a type of birth that is already in demand, and therefore it is believed that women will not be reluctant to enter the study, as **it does not expose them to any additional risk compared to the decision they have already made.**

The health care professionals who carry out the intervention and follow-up will be the same midwives who make up the hospital's midwifery team. In most cases, they are people who know how to manage a full delivery in a birth pool. Those who have only practised with dilatation will be able to learn the technique as **they will all receive training** through the most complete and up-to-date course. Thus, they will be fully capable of developing the intervention of the study. Also, the health professionals in charge of collecting data are going to be trained to reach a comparable use of the technology.

The **budget of the study is not exaggerated**, because all the participating hospitals do dispose of the equipment required to carry out the intervention and, apart from the statistician and the computer scientist, no additional personnel will need to be hired.

Summarising this information, it is concluded that **this study has a feasible realisation.**

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16. ANNEXES

16.1. ANNEX 1 - Pregnancy risk groups

Table: *Pregnancy risk groups according to the 'Protocol de seguiment de l'embaràs a Catalunya'* (27). *BMI: body mass index. WHO: World Health Organization.*

PREGNANCY RISK GROUPS	
NON-RISK	**LOW-RISK**
Although there is no such thing as a total absence of risk, "a pregnancy in which it is not possible to demonstrate any of the risk factors that are systematically sought is classified as normal".	If ≥1 of the following factors are identified: ● **Pelvic abnormality** ● **Low height** ● **Inadequate pregravid BMI** ● **Unwanted pregnancy** ● **Inadequate vaccination status** ● **Cardiovascular risk WHO I**
MEDIUM-RISK	
If ≥1 of the following factors are identified: ● **Very early or old age** ● **Multiparity** ● **History of placental pathology** ● **History of obstetric pathology in previous pregnancies** ● **History of intrauterine growth retardation and low birth weight neonates** ● **History of dystocic labour** ● **Cardiovascular risk WHO II** ● **Previous caesarean** ● **Previous induction**	● **Mild preeclampsia** ● **Unfavorable socio-economic conditions** ● **Victim of gender violence** ● **Tobacco habit** ● **Risk of isoimmunization** ● **Hereditary family history that may interfere with the normal course of pregnancy** ● **Well-controlled and diet-corrected gestational diabetes** ● **Previous uterine surgery** ● **Short intergeneric period** ● **First trimester metrorrhagia**

• **Personal antecedents of mental pathology** • **Current controlled and stable mental pathology** • **Previous sterility**	• **Infection risk** • **Insufficient or inadequate monitoring during current pregnancy**
HIGH-RISK	
If ≥1 of the following factors are identified: • **Morbid obesity** • **History of abortion** • **Previous chromosomal abnormality** • **Previous ectopic pregnancy** • **Previous gestational trophoblastic malignancy** • **Oligohydramnios or polyhydramnios** • **Gestational diabetes corrected with diet and insulin** • **Current serious mental pathology** • **Twin pregnancy** • **Isoimmunisation Rh(D)**	• **History of preterm birth** • **Severe pre-eclampsia** • **Endocrinopathies** • **Cardiovascular risk WHO III** • **Pre-pregnancy hypertension** • **Severe anaemia** • **Suspected foetal malformation** • **Treatment with anticoagulants until delivery or coagulopathies** • **Maternal infection diagnosed during pregnancy** • **History of uterine cervical incompetence** • **Prolonged pregnancy**
VERY HIGH-RISK	
If ≥1 of the following factors are identified: • **Serious associated pathology** • **Previous perinatal death** • **Type 1 or 2 diabetes** • **Cardiovascular risk WHO IV** • **Syndrome of dependence on alcohol and/or other drugs** • **Diagnosed uterine malformations that hinders the development of the pregnancy**	• **Delayed intrauterine growth** • **Confirmed foetal malformation** • **Abnormal placental status** • **Eclampsia** • **Threatened preterm labour** • **Premature rupture of membranes** • **Multiple pregnancy**

16.2. ANNEX 2 - Birth plan of Hospital Santa Caterina (104)

Pla de naixement | Part hospitalari

Introducció

L´objectiu del nostre centre és oferir una atenció al part mínimament medicalitzada, respectada i fisiològica.

Seguint aquesta línia, oferim la possibilitat que decidiu el màxim nombre d'aspectes segons les vostres expectatives emocionals, afectives i culturals.
Aquest document és l'eina per a que expresseu les vostres preferències i necessitats, dins les alternatives que us podem oferir, i ens arribin a nosaltres.

Per informar-vos a l'hora de fer aquest Pla de Naixement, consulteu el nostre Protocol de Part que el trobareu a la nostra pàgina web. A més, durant l'embaràs, els professionals que us atenen us donaran tota la informació necessària per tal que prengueu decisions informades.

Cal recordar que per poder acollir-se a aquest Pla de Part és necessari que l'embaràs i el part siguin considerats de risc baix en tot moment. Per això, l'aparició d'algun factor que augmenti el risc pot suposar la modificació o sortida d'aquest Pla.

Atenció general durant el part

S' intentarà que l'assistència durant tot el procés de dilatació i part sigui a la mateixa sala, on es mantindrà un ambient íntim i acollidor.

Durant el procés de part vull estar

- ☐ Sense acompanyant
- ☐ Amb un/ una acompanyant

En cas de necessitat de part instrumentat, sempre que sigui possible prefereixo estar:

- ☐ Sense acompanyant
- ☐ Amb un/a acompanyant

Oferim diferents alternatives relacionades amb l'espai físic per tal que us sentiu còmodes.

Preferències relacionades amb l'espai físic :

- ☐ Escoltar música
- ☐ Aromateràpia
- ☐ Llum
- ☐ Foscor

L'hospital també posa a la vostra disposició material de suport durant el procés del part, tot i que també us podeu dur el vostre propi material.

He pensat en utilitzar el següent material de suport:

- ☐ Banyera
- ☐ Pilota
- ☐ Coixins
- ☐ Mirall
- ☐ Cadira de parts
- ☐ Combi TracK
- ☐ Màrfegues
- ☐ Altres:.....

Procurarem que disposeu de la màxima llibertat de moviments i la possibilitat d'adoptar la posició que trobeu més còmode dins l' espai de les nostres instal· lacions, sempre controlant el benestar dels dos, mare i fill/a , de la manera més adequada.

M'agradaria que el control del benestar del meu fill/a es faci amb:

- ☐ Només auscultació
- ☐ Amb monitoratge electrònic intermitent
- ☐ Amb monitoratge electrònic continuat
- ☐ No tinc preferències

La hidratació durant el part és important i, en general, es poden beure líquids clars durant la dilatació (aigua, te, cafè, infusions, sucs sense polpa, begudes isotòniques...). La hidratació pot ser oral o endovenosa.

Pel que fa a la hidratació durant el part:

- ☐ Portaré begudes de la meva elecció
- ☐ Prefereixo no beure durant la dilatació
- ☐ No tinc preferències

El nostre protocol crei adient i inclou, posar una via venosa per tal de permetre l'administració de tractaments en cas necessari. Si el part es desenvolupa sense complicacions, la via es mantindrà sense connectar cap sèrum.

M'agradaria que:

- ☐ En cas que sigui necessari administrar-me un medicament, vull que se m'informi
- ☐ No tinc preferències

Altres opcions:

- ☐ M'agradaria fer servir la meva pròpia roba
- ☐ M'agradaria fer servir la roba que l'hospital posi a la meva disposició

Existeixen diversos mètodes per alleujar el dolor durant el procés del part.

Pel que fa a l'alleujament del dolor, m'agradaria:

- ☐ Tenir/provar un part sense anestèsia
- ☐ Que em posessin anestèsia el més aviat possible, quan estigui indicat pel professional
- ☐ Utilitzar mètodes farmacològics si ho necessito, quan estigui indicat pel professional
- ☐ Peridural a baixa dosi
- ☐ Peridural
- ☐ Utilitzar els següents mètodes no farmacològics:
  - ☐ Estimulació cutània (massatge superficial, pressió/massatge i aplicació superficial de calor o fred)
  - ☐ Banyera o dutxa d'aigua calenta
  - ☐ Massatges
- ☐ Provar l'ús de teràpies complementàries i/o alternatives, que jo aportaré:
  - ☐ Homeopatia
  - ☐ Flors de Bach
  - ☐ Acupuntura
  - ☐ Naturopatia
  - ☐ Aromateràpia

Atenció durant el moment del naixement

Procurarem que disposeu de la màxima llibertat de moviments i escolliu la posició més còmode, tot controlant el vostre fill/a amb la mínima intervenció possible. Procurarem, sempre que es pugui, realitzar una protecció activa del perineu, i en cas d' episiotomia no es farà de forma rutinària, sinó quan sigui estrictament necessari (de recurs).

L'esponderament és la força que fa la dona per acompanyar la sortida del nadó. En un part normal només s'ha de fer si se sent la necessitat de fer– ho i amb dilatació completa. Empènyer en altres moments o de forma continuada no està indicat, excepte en situacions com l'ús d'anestèsia epidural. Es pot pinçar i tallar el cordó umbilical poc després de la sortida del nadó o es pot esperar a que deixi de bategar. Tant tu com l'acompanyant podeu tallar-lo, si voleu.

Respecte a les meves preferències durant el naixement, m'agradaria que:

- ☐ El meũ/va acompanyant pugui estar al meu costat
- ☐ El meu/va acompanyant pugui veure el naixement
- ☐ Tenir un mirall per veure el naixement
- ☐ Posar-me en la posició en que em trobi millor pels esponderaments
- ☐ Provar de tenir un part a l'aigua
- ☐ Que es tallés el cordó quan deixi de bategar
- ☐ M'és indiferent el moment en el que es talli el cordó
- ☐ Si és possible, que jo o el meu/va acompanyant puguem tallar el cordó

Pel que fa a la rebuda del meu fill/a m'agradaria:

- ☐ Rebre en braços al meu fill/a immediatament quan neixi
- ☐ Esperar a que se li realitzin els primers controls al meu fill/a, abans de rebre'l en braços.
- ☐ Tenir-lo en contacte pell amb pell.
- ☐ Que pogués estar en contacte pell amb pell amb el meu/va acompanyant.
- ☐ Que es valorés al meu fill/a sobre meu.
- ☐ Que se li realitzessin les primeres cures pell amb pell
- ☐ Iniciar l'alletament a sala de parts
- ☐ En caș que el naixement sigui per cesària, m'agradaria que jo o el meu/va acompanyant pogués̀sim realitzar el contacte pell amb pell.
- ☐ M'agradaria que no separessin el nadó de mi a menys que sigui estrictament necessari.

En relació al període de deslliurament (sortida de la placenta):

Esperarem el màxim acceptat per l'evidència científica (3 0 minuts)

Puerperi immediat

Als pocs minuts del naixement està protocol·litzada **l'administració de la vitamina K** als nadons donat que és una mesura d'efectivitat demostrada científicament per reduir el risc de complicacions hemorràgiques. La via recomanada és la intramuscular (injecció), però també es pot administrar per via oral (menys efectiva).

- ☐ Prefereixo que s'administri al meu fill/a la vitamina K intramuscular
- ☐ Prefereixo que s'administri al meu fill/a la vitamina K oral

Es recomana també la **utilització de pomada antibiòtica** per a la profilaxi ocular (evitar infeccions als ulls).

- ☐ Entenc i accepto l'ús de la pomada
- ☐ Preferiria retardar l'ús de la pomada (menys interferència visual mare fill)

Després del part, estareu una hora a la mateixa sala, abans de passar a la planta de maternitat.

Alletament

M'agradaria que l'alletament fos:

- ☐ Alletament matern a demanda
- ☐ Alletament artificial
- ☐ Alletament mixt
- ☐ No vull que se li proporcioni cap tipus d'aliment al meu fill/a sense consultar-me
- ☐ No vull que se li proporcioni xumet al meu fill sense consultar-me

Estada a l'hospital

El nostre hospital ofereix la possibilitat d'Alta el més aviat possible a les dones del nostre ASSIR que hagin tingut embarassos i parts de baix risc i sense complicacions.

El programa ofereix la possibilitat a aquelles dones que ho vulguin, de tornar a casa seva abans de 24h. i amb la visita d´una llevadora al domicili el dia següent. En el cas de fora de zona, s' hauria de portar un document signat de la llevadora del seu ASSIR/CAP.

- ☐ M'agradaria poder-me acollir al programa: Part a l'hospital, Llevadora a casa
- ☐ No tinc preferències en aquest aspecte

Altres necessitats

Les expectatives i les necessitats al voltant de l'atenció a rebre durant el part i el naixement depenen també de les característiques individuals de cada persona i de la seva cultura d'origen. Si teniu una **necessitat o requeriment específic** comenteu-lo amb els professionals de l'equip obstètric (obstetres i llevadores) i es valorarà si podem atendre la vostra sol·licitud.

- ☐ Hi ha alguna necessitat que no quedi coberta i que voldries comentar amb l'equip obstètric?

  _____
  _____
  _____
  _____

En cas de **dificultat lingüística** a l'hora de comunicar-vos a l'hospital, tenim la possibilitat de contactar amb mediadores d'origen xinès, magrebí i subsaharià, que es troben disponibles en horari de matí. Marqueu si voldríeu fer ús d'aquest recurs.

- ☐ Mediadora xina
- ☐ Mediadora magrebí
- ☐ Mediadora subsahariana

Jo _____ amb DNI _____

conec el contingut d'aquest document, he rebut informació sobre el part i he escollit les opcions que m' han semblat oportunes.
Manifesto també conèixer i acceptar les condicions per rebre atenció segons aquest Protocol de baix risc i també el meu deure de mantenir el respecte degut a les normes establertes en el centre i al personal que hi presta serveis

En tot cas, em reservo el dret de canviar total o parcialment les decisions que expresso en aquest document en qualsevol moment al llarg del procés.

Equip d' Obstetricia Professional:	**Accepto aquest Pla de naixement**
Data/signatures	**Data/signatures**

16.3. ANNEX 3 - Informative document

FULL D'INFORMACIÓ A LA PARTICIPANT

Nom de l'estudi: Seguretat de la immersió en aigua durant la segona fase del part en embarassades de baix o nul risc

Centre assistencial:

Investigador/a principal:

INTRODUCCIÓ

Ens dirigim a vostè per informar-la sobre un estudi d'investigació al que volem invitar-la a participar.

L'estudi ha estat aprovat pel Comitè d'Ètica i Investigació Clínica (CEIC) de l'Hospital Universitari Josep Trueta de Girona, d'acord amb la legislació vigent, i amb respecte als principis enunciats en la declaració d'Hèlsinki i a les guies de bona pràctica clínica.

La nostra intenció és que rebi la informació correcta i suficient perquè pugui avaluar i jutjar si vol o no participar-hi. Per això li preguem que llegeixi aquest full informatiu amb atenció i nosaltres li aclarirem els dubtes que li puguin sorgir. A més, podeu consultar-ho amb les persones que considereu oportú.

PARTICIPACIÓ VOLUNTÀRIA: Què passa si decideixo abandonar l'estudi?

La seva participació en aquest estudi és voluntària i pot canviar la seva decisió en qualsevol moment, revocant el consentiment informat, sense necessitat de justificar-se i sense que es produeixi cap alteració en la relació amb el seu metge ni cap prejudici en la seva atenció sanitària.

DESCRIPCIÓ GENERAL DE L'ESTUDI

Per què és necessari aquest estudi?

El part natural és aquell en què la dona no té la intenció d'utilitzar analgèsia epidural per tolerar el dolor del part. La dona ingressa a l'hospital durant el període de dilatació i, des d'aquest moment, gaudeix de lliure moviment i té a la seva disposició diferents tècniques que poden alleugerir el dolor que causen les contraccions. El part evoluciona de manera fisiològica i sense intervencions, només amb l'acompanyament dels i les llevadors/es.

El part a l'aigua és una tècnica emprada des de fa molts anys per parir que actualment s'està implantant en alguns hospitals. Són moltes les dones que tenen interès per tenir un part natural i involucrar una banyera de parts en la seva experiència. Tot i això, no és una tècnica que ofereixen tots els hospitals de Catalunya: de fet, només 8 tenen una banyera de parts a la seva disposició. I no tots ells permeten la totalitat del part a dins de l'aigua: n'hi ha que, un cop arribats a l'expulsiu, que és la segona fase del part, et fan sortir. Això és perquè els preocupa que la seguretat de l'expulsiu no sigui suficient, i prefereixen evitar possibles complicacions, sobretot pel nadó, que han estat descrites a la literatura com el trencament del cordó umbilical, la pneumònia, l'aspiració d'aigua dolça o l'augment de temperatura del bebé.

Sembla que els estudis científics cada vegada estan demostrant amb més evidència que el part a l'aigua és segur, a través d'estudis que diuen que la probabilitat de tenir aquestes complicacions és semblant al part al terra, i que les que sorgeixen no tenen repercussió en el bebé, ja que són molt lleus. De fet, hi ha alguns centres de Catalunya que porten anys atenent parts a l'aigua, i que han tingut molt bona experiència i resultats: entre ells, escurça el temps del part, millora les contraccions i el dolor, aporta més llibertat de moviment en flotació, més sensació de seguretat i empoderament i les dones que hi pareixen gaudeixen de més satisfacció.

Si finalment es determina que el part a l'aigua és segur, es podria implementar com una opció més a l'hora d'escollir entre d'altres, quan una dona està interessada en tenir un part natural.

Quins són els objectius de l'estudi?

L'objectiu de l'estudi és demostrar que el part a l'aigua, per a les dones considerades de baix risc o sense risc, és una pràctica segura que no resulta en més complicacions ni per la mare ni pel nen respecte el part natural a terra. A més, també es vol demostrar que les dones que pareixen dins de l'aigua tenen una millor experiència de part.

Quants centres hi participen i quant de temps dura?

En aquest estudi una totalitat de 8 hospitals d'arreu de Catalunya hi participaran. Són el següents: Hospital Germans Trias i Pujol (Badalona), Hospital de Tortosa Verge de la Cinta (Tortosa), Hospital Santa Caterina (Salt), Hospital de Palamós (Palamós), Fundació Sanitària de Mollet (Mollet), Hospital Universitari Josep Trueta (Girona), Hospital General de Granollers (Granollers) i Hospital Clínic de Barcelona (Barcelona).

L'estudi està previst que tingui una duració de 3 anys i mig.

Quines característiques han de reunir les pacients per participar en l'estudi?

Cal complir uns criteris molt estrictes per a ser candidata a tenir un part natural. Cal que el seu embaràs sigui considerat de baix risc o sense risc a l'arribar al tercer trimestre. Aquest risc es valorarà a la visita de la setmana 35 o 36 d'embaràs, cap al final, amb els resultats de l'analítica, el cultiu recto-vaginal i l'ecografia.

A més, en el moment del part, es tornarà a valorar el risc ja que és possible que hagi variat, tot tenint en compte el seu estat general i el del nadó. Si tot i això es considera que vostè no presenta risc o bé és molt baix per tenir complicacions durant el part, tindrà l'opció de parir en una banyera d'aigua o bé en una sala de parts naturals, sense la banyera.

En què consisteix la meva participació en l'estudi?

Si vostè compleix totes les característiques per a ser candidata a tenir un part natural, en el moment del part serà lliure de decidir com i on vol parir: si vol tenir un part dins la banyera o bé si el vol tenir a fora (un part a terra). Serà una decisió que podrà prendre al mateix moment.

De la mateixa manera se l'acompanyarà tant si escull un tipus de part com un altre. Si elegeix el part a l'aigua, ha de saber que tot el personal que l'atendrà durant el procés de part haurà rebut formació de com assistir un part a l'aigua. És possible que en algun moment el/la llevador/a li demana que surti de la banyera perquè alguna complicació pot haver aparegut, que és més senzilla de resoldre fora de l'aigua. Algun dels motius poden ser un registre cardiotogràfic que avisi de patiment fetal, sagnat excessiu, aigües meconials tenyides, distòcia d'espatlles que requereix maniobres, signes d'infecció materna (febre, taquicàrdia) o alteració de constants vitals.

De vegades, també es requereix l'administració de fàrmacs que fan discontinuar la immersió a l'aigua, com és en el cas de sol·licitar l'analgèsia epidural i també quan el part queda estacionat, on es necessita l'ajuda d'oxitocina.

Per altra banda, si elegeix tenir un part a terra podrà utilitzar la resta de material del que es diposa a la sala de parts naturals (pilotes inflables, camilla, coixins, compresses calentes…).

Un cop hagi parit, es quedarà ingressada a la planta de l'hospital durant 24-48h i, en el cas que ho desitgi i no hi hagi contraindicació mèdica, podrà demanar l'alta precoç. Posteriorment, podrà anar a casa, com diu el procediment habitual.

Coincidint amb la visita de tancament del postpart amb la llevadora, 6 setmanes després d'haver donar a llum, haurà d'omplir una enquesta valorant la seva experiència de part.

BENEFICIS: Quins beneficis obtindré de la meva participació a l'estudi?

Amb la seva participació en aquest estudi tindrà l'opció d'escollir tenir un part a l'aigua. A més, ajudarà a ampliar el coneixement científic sobre aquest tema, i poder contribuir així a optimitzar els protocols d'aquesta pràctica i per a ser utilitzat per altres futures dones que hi vulguin parir.

POSSIBLES RISCS: Quins riscs assumeixo si participo en l'estudi?

El fet de participar en aquest estudi no es considera cap risc afegit davant la seva decisió del tipus de part.

PROTECCIÓ DE DADES PERSONALS I CONFIDENCIALITAT: Com s'assegurarà la confidencialitat de les seves dades?

La informació recollida en aquest estudi serà introduïda en una base de dades per al seu anàlisi. Ningú, excepte el seu metge i el personal directament relacionat amb aquest estudi, coneixerà la seva identitat, i en cap cas el seu nom apareixerà en un document públic. L'ús comercial d'aquestes dades està estrictament prohibit.

Tota la informació es guarda i gestiona de manera segura i confidencial, de conformitat amb el que estableix la Llei Orgànica 03/2018, del 5 de desembre i del Reglament (UE) 2016/679 del Parlament Europeu de 27 d'abril de 2016 de protecció de dades (RGPD).

Cada participant rebrà un nombre que utilitzaran els investigadors per tractar les dades. Únicament els investigadors d'aquest estudi podran relacionar la seva identitat amb els codis. Les dades que es recullin podran compartir-se amb investigadors d'altres centres nacionals i estrangers, amb finalitat únicament investigadora. Els investigadors d'altres centres no coneixeran dades que revelin la seva identitat.

En tot cas, té dret a exercitar els drets d'oposició, accés, rectificació i cancel·lació, instal·lació en l'àmbit reconegut per RGPD. També pot limitar el tractament de dades que siguin incorrectes, sol·licitar una còpia o que es traslladin a un tercer (portabilitat) les dades que vostè ha facilitat per a l'estudi.

L'investigador està obligat a conservar les dades recollides per a l'estudi com a mínim fins a 25 anys després de la seva finalització. Posteriorment, la seva informació personal només es conservarà pel centre per a la cura de la seva salut i per a altres fins d'investigació científica si vostè hagués atorgat el seu consentiment per a això, i si així ho permet la llei i els requisits ètics aplicables.

Li recordem que les dades no es poden eliminar encara que deixi de participar en l'estudi per garantir la validesa de la investigació i complir amb els deures. Així mateix, té dret a dirigir-se a l'Agència de Protecció de Dades si no quedés satisfeta.

DIFUSIÓ DELS RESULTATS: Què se'n farà dels resultats obtingut de l'estudi?

Un cop s'hagi finalitzat l'estudi, s'extrauran els resultats i s'elaboraran conclusions. Es preveu la publicació dels resultats a revistes científiques, tant si el resultat és positiu com si és negatiu. Tot aquest procés es farà sempre respectant l'anonimat de la participant. D'aquesta manera, altres centres assistencials se'n podran beneficiar i podran implementar el part a l'aigua si es demostra que aquesta és una pràctica segura.

COMPENSACIÓ ECONÒMICA: Tindré alguna compensació econòmica si participo a l'estudi?

Els investigadors que participen en l'estudi no reben cap tipus de benefici econòmic. La participació a l'estudi és voluntària i per tant, no serà remunerada. Tampoc li comportarà cap cost econòmic addicional a la pràctica clínica habitual.

DUBTES: Amb qui he de contactar davant qualsevol dubte o problema que sorgeixi?

Per exercir els seus drets, o si té qualsevol dubte o pregunta sobre l'estudi, estem sempre a la seva disposició i pot posar-se en contacte amb l'equip investigador, al telèfon _____ o al correu electrònic _____.

Moltes gràcies per la seva col·laboració.

Signatura de/la pacient

Signatura de l'investigador/a

Nom:
Data:

Nom:
Data:

16.4. ANNEX 4 - Informed consent document

FULL DE CONSENTIMENT INFORMAT DE LA PACIENT

TÍTOL DE L'ESTUDI: Seguretat de la immersió en aigua durant la segona fase del part en embarassades de baix o nul risc

Jo (nom i cognoms) _____,

amb DNI _____, declaro que:

- He llegit la fulla informativa que se m'ha entregat
- He pogut fer les preguntes que m'han sorgit i aquestes s'han respost de forma satisfactòria
- He rebut informació suficient sobre l'estudi
- He parlat amb (nom i cognoms de l'investigador/a): _____

Declaro també que la meva participació és voluntària i que entenc que puc retirar-me de l'estudi:

- Quan vulgui
- Sense haver de donar explicacions
- Sense que això repercuteixi en el meu seguiment i cures mèdiques

De conformitat amb el que estableix el Reglament (UE) 2016/679 del Parlament i del Consell, de 27 d'abril de 2016, relatiu a la protecció de les persones físiques pel que fa al tractament de dades personals i a la lliure circulació d'aquestes dades i pel qual es deroga la Directiva 95/46/CE (Reglament general de protecció de dades) (DOUE 4.5.2016), declaro haver estat informada de:

- L'existència d'una base de dades on s'inclouran les meves dades de caràcter personal
- De la finalitat de la seva recollida i dels destinataris de la informació
- Del procés de codificació de les dades
- De la disponibilitat d'exercir els drets d'accés rectificació, cancel·lació i oposició dirigint-me per escrit al titular de la base de dades

I consenteixo que les dades clíniques referents al meu embaràs i part siguin emmagatzemades en un fitxer automatitzat, la informació del qual podrà ésser utilitzada exclusivament amb finalitats científiques.

Dono lliurement la meva conformitat per participar en l'estudi.

_____	_____
Firma de la pacient	Firma de l'investigador/a
Data:	Data:

16.5. ANNEX 5 - Withdrawn consent

REVOCACIÓ DEL CONSENTIMENT

Jo, (nom i cognoms)_____

amb DNI_____, revoco el consentiment informat prèviament firmat de participar en l'estudi "Seguretat de la immersió en aigua durant la segona fase del part en embarassades de baix o nul risc".

_____

Firma de la pacient

Data:

16.6. ANNEX 6 - APGAR score

***Table**: APGAR score* (105).

Signo	0	1	2
Frecuencia cardiaca	Ausencia de latido	Menos de 100 latidos por minuto	Más de 100 latidos por minuto
Respiración	Ausente	Lenta, irregular	Buena, llanto
Tono muscular	Flácido	Extremidades algo flexionadas	Movimiento activo
Irritabilidad refleja	Sin respuesta	Quejido, mueca	Tos, estornudo, llanto, retraimiento vigoroso
Coloración	Azul o pálido	Cuerpo rosado con extremidades azules	Completamente rosado

16.7. ANNEX 7 - Silverman's test

***Figure 22**: Silverman's test score* (106).

16.8. ANNEX 8 - The Childbirth Experience Questionnaire (Spanish version)

The Childbirth Experience Questionnaire – CEQ (Spanish version)

Cuestionario sobre tus experiencias durante el parto

¡Para ti que acabas de ser madre!

Uno de los objetivos de los profesionales es, en el área materno-infantil de tu departamento de salud, el de ofrecer una experiencia positiva durante el parto. Así pues, el propósito de este cuestionario es conocer tus experiencias durante el parto, y comparar tus respuestas con las de otras madres, para poder evaluar la atención que ofrecemos. Por favor, es importante que respondas todas las cuestiones.

Hay respuestas en las que debes marcar con una cruz la casilla y respuestas en las que debes marcar con una cruz una línea:

Ejemplo 1. Lee la frase y marca con una cruz la casilla que mejor describa tu respuesta.

Como fruta cada día.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☒	☐	☐

Ejemplo 2. Lee la frase y marca con una cruz el tramo de línea que mejor describa tu respuesta.

¿Te gustan las manzanas?

Nada, en absoluto — Son lo mejor que hay

El cuestionario empieza en la próxima página.
¡Gracias por darnos tu punto de vista y por colaborar con tus respuestas!

1. El parto fue como esperaba.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

2. Me sentí fuerte durante el parto.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

3. Tenía miedo durante el parto.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

4. Me sentí capaz durante el parto.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

5. Me sentí cansada durante el parto.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

6. Me sentí feliz durante el parto.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

7. Tengo muchos recuerdos positivos del parto.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

8. Tengo muchos recuerdos negativos del parto.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

9. Me ponen triste algunos recuerdos del parto.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

10. Me pareció que podía elegir entre estar levantada y moviéndome o estar acostada.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

11. Me pareció que podía elegir la posición cuando tuve que empujar para que saliera el bebé.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

12. Me pareció que podía elegir entre diferentes métodos para calmar el dolor.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

13. La matrona me dedicó la atención necesaria.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

14. La matrona le dedicó la atención necesaria a mi pareja.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

15. La matrona me mantuvo informada sobre lo que estaba pasando durante el parto.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

16. La matrona entendió mis necesidades.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

17. Me sentí muy bien atendida por la matrona.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

18. Me dio seguridad la competencia de los profesionales.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

19. Me sentí capaz de manejar bien la situación.

Totalmente de acuerdo	Bastante de acuerdo	Bastante en desacuerdo	Totalmente en desacuerdo
☐	☐	☐	☐

20. En general, durante el parto, ¿sentiste dolor?

Ningún dolor — El peor dolor imaginable

21. En general, durante el parto, ¿sentiste que tenías control?

Nada de control — El máximo control posible

22. En general, durante el parto, ¿te sentiste segura?

No me sentí nada segura — Me sentí segura del todo

Escribe aquí otros comentarios que quieras hacer:

¡Muchas gracias por tu colaboración!