

Participant Information Sheet

Title	Water birth Access at Term to Estimate Risks and Benefits In Research Cohorts in Trial in Hospital: a prospective cohort feasibility study
Short Title	The WATERBIRTH study
Principal Investigator	Professor Sue Kildea
Location	Mater Mothers' Hospitals, Brisbane

Mater Research is a world class medical research institute based at South Brisbane specialising in cancer, maternity and obesity related research. Mater's 200 researchers are based in clinical settings at the Mater Health Services and laboratories at the Translational Research Institute (TRI).

In 2013, Mater Research and The University of Queensland formalised a long-standing relationship to form the Mater Research Institute – University of Queensland (MRI-UQ). MRI-UQ is an alliance between the two leading institutions working together to achieve the best possible research discoveries in health.

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you are expecting to give birth to a healthy, full-term baby at Mater Mother's Hospital (South Brisbane). The aim of this project is to determine the feasibility of a larger study which would test the safety, effectiveness and cost of water birth compared to land birth for low risk women.

The research project is assessing a new procedure at this hospital for labour and birth called water birth.

This Participant Information Sheet tells you about the research project. It explains what the procedure involves. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your midwife / doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign a consent form. By signing it you are telling us that you:

- understand what you have read
- consent to take part in the research project
- consent to have the procedure (water birth or land birth) described on Page 2
- consent to the use of your personal and health information as described.

2 *What is the purpose of this research?*

Water immersion refers to the woman's abdomen (or 'stomach') being below the surface of the water during labour; baths, pools and spas of different depths may be used. Many women in Australia are now choosing to use warm water immersion during labour for comfort and pain management as it allows easy movement, reduces pain, decreases the need for epidural, and speeds up the first stage of labour. Mater Mother's Hospital supports healthy women with a normal pregnancy to consider warm water immersion in labour to help promote normal birth. However women are currently asked to exit the bath when their baby is close to being born.

Water birth occurs when a baby is born fully underwater; the baby is then immediately brought head first to the surface. A specially designed pool that is deeper and bigger than a normal bath is used. Studies report the benefits of water birth for women include increased satisfaction due to greater relaxation, ability to change positions easily and a greater sense of control and privacy.

The highest quality research (systematic review) reported that for babies born underwater there were no differences in their condition 5 minutes after birth (Apgar score), whether they were admitted to the neonatal nursery, or whether they had an infection, compared to babies born on 'land' (e.g. in a hospital bed). The research results so far are reassuring about the safety of water birth for babies; but none of the studies were big enough to definitely say that water birth is safe.

That's why we are planning this study:

- to monitor outcomes when water birth is introduced at the Mater Mothers' Hospital and
- to find out if we may be able to conduct a larger study to test if water birth is as safe as land birth for babies.

In our current study we specifically want to see if sufficient numbers of women with low-risk pregnancies will:

- agree to be involved in this study
- actually have a water birth.

We are also interested to find out if women would agree to be randomly allocated to either water birth or land birth in a future study.

This information will help us work out whether we can conduct a larger study and to develop the design of a larger study which would compare outcomes for babies born under water to babies born on land. The larger study would be an international study and would require several thousand women to participate.

3 What does participation in this current research study involve?

At approximately 36 weeks of pregnancy if you meet the study criteria (you are a healthy woman, weigh less than 100kg, you will not require continuous monitoring of the baby's heart rate in labour, you are only having one baby and the baby's head is coming first) you are welcome to consider participation. Before you decide whether or not you would like to participate you may wish to discuss the study with your family/friends/support people or your midwife/doctor.

When you arrive at the hospital in labour, the midwife / doctor will check if you still meet the study criteria (e.g. normal labour, you and baby are well). If you do meet the criteria you will be asked to sign a consent form and *you can choose* whether you would like to access a room with a birth pool (planned water birth) or a standard room (planned land birth).

If you plan to have an underwater birth: you will be transferred to a room with a specialist birth pool and you will be looked after by a midwife who is trained to provide water birth care (as long as both the room and the midwife are available). Providing you are happy to stay in the bath for birth, and there are no reasons for you to get out of the water, you may proceed to give birth to your baby under water, with your baby brought to the surface immediately after birth.

Of course you have the option to enter and leave the pool at any point if you wish, and you may also change your mind and give birth on land instead. It is Mater Mothers' Hospital policy to recommend active management of third stage labour (with an injection of medication to speed up the birth of the placenta). To have active management of third stage you will be required to leave the pool within a few minutes of giving birth and move to a mat on the floor or onto a hospital bed (for example). If you wish to give birth to your placenta naturally (physiological third stage) you must request to do so and you may do this in or out of the pool – this is your choice.

If you plan to have a land birth: you will be transferred to a room with a standard bath which you may choose to use during first stage labour (but you do not need to use the bath). You will not be able to give birth in the bath as they are not big enough or deep enough to do so safely or comfortably. You will give birth to your baby in any position that feels comfortable on land. It is Mater Mothers' Hospital policy to recommend active management of third stage labour (with an injection of medication to speed up the birth of the placenta). If you wish to give birth to your placenta naturally (physiological third stage) you must request to do so – this is your choice.

After birth the research team will use information that is routinely collected on the hospital databases and your medical charts about you and your baby (e.g. type of birth, baby's birth weight) to analyse the results of the study. This information will be de-identified i.e. not connected to your name, medical number or any identifying details.

Approximately six weeks following your birth we will send (email or post) a short survey about your childbirth experience and satisfaction with your care. The survey will take about 20 minutes to complete. If you prefer the survey to be posted, we will include a stamped addressed envelope for you to return it to us.

4 ***What do I have to do?***

Mater Mother's Hospital does not currently offer water birth. All labouring women currently using water immersion are asked to leave the bath before the birth of their baby. If you wish to have an opportunity to have a water birth, then you will need to be a participant in this study.

Before you make any decision regarding your participation you may wish to talk further with a member of the research team (study investigators or research assistant) for additional information or clarification. When you arrive at the hospital in labour, the midwife will check that you still meet all the criteria for study. If you do meet the criteria then you will need to decide if you plan to have a water birth or a land birth.

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

5 ***Other relevant information about the research project***

Researchers, midwives, maternity consumers, obstetricians, neonatologists (doctors specialising in the care of newborn babies) and at the *Midwifery Research Unit* and *Mater Research* are working together to oversee this research study. The purpose of this feasibility study is to see if a larger study is possible. Over a 12-month period we estimate approximately 600 women will take part at the Mater Mother's Hospital. There is an independent Data Safety and Monitoring Committee overseeing the study.

6 ***Do I have to take part in this research project?***

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage including during labour. If for example if you plan to have a water birth but want to get out of the pool during labour you are free to do so – we would still like you to remain in the study. You are also free to return to the pool unless you are actively engaged in birthing your baby.

If you do decide to take part, you will be given a Participant Information and Consent Form to sign (the information is mostly covered in this letter) and you will be given a copy to keep. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your treatment, your relationship with those treating you or your relationship with Mater Mothers' Hospital.

7 ***What are the alternatives to participation?***

You do not have to take part in this research project to receive care at this hospital. Other options are available to women who do not want to be included in the research. For example, not using water immersion during labour or using water immersion during labour in a bath and giving birth to the baby out of the water.

8 *What are the possible benefits of taking part?*

The study is not intended to directly benefit participants although previous research confirms that possible benefits of water birth include increased satisfaction with your birth experience. You will assist, however, in determining whether it is possible to conduct a larger study of water birth.

9 *What are the possible risks and disadvantages of taking part?*

The research is monitored by a Data Safety and Monitoring Committee who will investigate any unexpected or poor outcomes in mothers and their babies. This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and to prevent study researchers, hospital staff, or participants from jumping to conclusions.

There has never been a proven case of a baby drowning during a water birth attended by a trained maternity care provider. However, there are four potential risks for babies born under water that you need to consider:

1. That your unborn baby may get too hot if you get too hot in the pool during labour. This is managed by closely monitoring your temperature and encouraging you to leave the pool if you feel too hot. When it comes time to pushing the midwife will make sure the water is 37-37.5 degrees (normal body temperature) so that your baby is born into water that is the same temperature as the water s/he has been living in inside the womb.
2. That your baby may gasp (breathe) underwater if it experiences 'fetal distress' (becomes unhealthy). To avoid this occurring, the baby's heart rate is monitored regularly to ensure it is normal. If it is not normal, or if any risk factors develop during labour (e.g. fast/slow heart rate, or meconium-stained liquor) then you will be asked to leave the pool.
3. That your baby may develop an infection after it is born. Although there is no evidence of increased risk of infection for babies who are born under water, this potential risk is managed by strict cleaning guidelines for all birth pools in birth suite.
4. That your baby's cord may snap under water causing your baby to lose blood until the cord is clamped. This is a rare event (approximately 1 in every 800 births) that can happen during any birth, whether in water or on land birth. However cord snap may be more common during water birth because the pool is relatively deep and we need to bring the baby's head to the surface of the water immediately after birth.

10 *What will happen to my baby's cord blood test samples?*

The research does not involve sampling your baby's cord blood. If your baby's cord blood is sampled for a medical reason then these results will be recorded in electronic database (this is routine) and will be examined along with other information about you and your baby which is routinely collected. The sample is immediately discarded.

11 *What if new information arises during this research project?*

Sometimes during the course of a research project, new information about the procedure that is being studied becomes available. If this happens, the researchers will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, you will still be able to access a normal bath for water immersion during labour but you will not be able to have a water birth. If you decide to continue in the research project you will be asked to sign an updated consent form.

12 *Can I have other treatments during this research project?*

Yes, you can access other forms of pain management in labour if you wish. However, if you decide to have epidural analgesia or narcotics (e.g. pethidine) during labour you must leave the pool and you will not be able to proceed to a water birth.

13 *What if I withdraw from this research project?*

You are free to withdraw from this research project at any time by filling in the attached 'withdrawal form' or notifying the research team. If you do withdraw from the research study you will not be able to access water birth at this hospital. If you do withdraw your consent during the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly, and to comply with law.

14 *Could this research project be stopped unexpectedly?*

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- difficulty recruiting women to participate
- water birth is shown to be safe and there is no need for further testing
- water birth is shown to have unacceptable risks.

15 *What happens when the research project ends?*

Depending on the results of the study, water birth may or may not become available as an option for all healthy women at the Mater Mother's Hospital.

Part 2 *How the research project is being conducted*

16 *What will happen to information about me?*

Routine personal and clinical information about you and your baby is recorded in your medical charts, your electronic health record and electronic hospital databases. By signing the consent form you consent to the research team (e.g. study investigators and research assistant) collecting and using personal information about you and your baby for the research study. Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law. Any information obtained in connection with this research project that can identify you will remain confidential as all participants will be assigned a unique study number. Any information about you or your baby which is stored on a Mater computer will be password-protected and accessed only by the research team. Research documentation in paper form will be archived for 15 years (as required by law) in a locked filing cabinet in the Midwifery Research Unit (Mater Health Services).

No identifying information will be used during statistical analysis and any presentations or publications emerging from this study will not contain any information which could identify you or your baby. In accordance with relevant Australian and Queensland privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team.

17 *Complaints and compensation*

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

18 *Who is organising and funding the research?*

This research project is being conducted by the Midwifery Research Unit and Mater Research and is being funded internally by these organisations.

19 *Who has reviewed the research project?*

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Mater Mothers' Hospitals and The Australian Catholic University (ACU). This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project you can contact the principal investigator, Professor Sue Kildea on (07) 3163 6335; or

Contact person

Name	Prof Sue Kildea
Position	Director, Midwifery Research Unit
Telephone	07 3163 6388
Email	sue.kildea@mater.uq.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Position	Research Ethics Co-ordinator
Telephone	3163 1585
Email	research.ethics@mmri.mater.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Local HREC Office contact (Single Site -Research Governance Officer)

Position	Research Governance Officer
Telephone	3163 8836
Email	research.governance@mmri.mater.org.au