

aQua

ASKING QUESTIONS
ABOUT ALCOHOL
IN PREGNANCY

at 6

Early School Years Follow-up



Dear AQUA study participant,

This pamphlet comes with a letter inviting you and your AQUA study child to take part in our Early School Years follow up (**AQUA at 6**). It gives you important information about what is involved in this project. It also has details about who to contact if you have any questions.

Before you decide to take part, it is important for you to understand why we would like to follow-up your child again at this time and what is involved. Please take the time to read this pamphlet carefully and discuss it with others if you wish.

If you and your child would like to take part, we will ask you to sign a consent form for the AQUA team to keep. We'll also ask you to sign and keep a copy of the consent form.

If you would like more information, please call us on **03 8341 6370**. Alternatively you can email us at **aquastudy@mcri.edu.au**. You will get the chance to ask questions when we call you in the next few weeks. You will also have the chance to ask questions on the assessment day before we start the activities.

Thank you for taking the time to consider taking part in this next phase of AQUA. All this information is also on our website at **www.mcri.edu.au/aquastudy**.



What is the purpose AQUA at 6 follow-up?

We know that many aspects of the mother's pregnancy, the child's early health and their family environment influence a child's learning and behaviour, especially in the early years. You have told us so much about you, your family and your child from the time they were a baby.

We did not find any developmental problems at age 2 years related to alcohol use in pregnancy in the many kids we assessed. However, early development is not always a good predictor of later development. It is critical that we assess this unique group of kids again once they have started school.

This is a time when kids develop complex social, academic and physical abilities. For example, they learn to fit in with their peers and a classroom routine, and literacy and numeracy skills mature.

The purpose of **AQUA at 6** is to gather detailed information on 6-7 year old kids about how they are coping with these new demands on their development. We will again be looking at whether occasional, low or moderate alcohol consumption in pregnancy is associated with any problems in the health and development of young children. For this, we invite you and your child to attend an assessment with a psychologist. This assessment looks at your child's thinking, reactions, learning, early academic achievement, communication and body movement. We are also interested in the facial development of the children. We have funds to take MRI scans of a subset of children to investigate possible brain characteristics.

What is the AQUA study?

The AQUA study is looking at possible effects on child development of drinking alcohol in pregnancy. We are especially interested if low amounts of alcohol were consumed or if there was the occasional binge drink.

Around 1,500 Victorian women have been participating in AQUA from early in their pregnancy. As you may remember, participation involved completing a questionnaire three times during pregnancy, one when the child was 12 months old and another at two years of age. Over 500 kids had a 3D photo taken of their face at 12 months and/or completed a developmental assessment when they were 2 years old. Where possible, we also collected placenta and cord blood and cheek brush swabs from the mum and baby.

The kids in in AQUA study will be turning six during 2018 and 2019. We have received funding to follow their development as they start their long journey through school. We are inviting you and your child to come to the Royal Children's Hospital again for an assessment. If you cannot come to the hospital, we might be able to visit you at home. We are calling this the AQUA Early School Years Follow-up or **AQUA at 6** for short.

Who is funding AQUA at 6?

AQUA at 6 is funded by the National Health and Medical Research Council.

Why are we invited to be in AQUA at 6?

You and your child are invited because you have taken part in the AQUA study from the beginning.

What does taking part in AQUA at 6 involve?

Taking part in **AQUA at 6** would involve attending the Royal Children's Hospital for:

- An assessment with a psychologist, looking at your child's thinking, reactions, learning, early academic achievement, communication and body movement. The assessment will take between 3 and 4 hours and is done by a psychologist or psychologist-in-training under close supervision. We will ask you to make a booking for a day and time that suits you. We may be able to visit you at home if you can't attend the hospital.
- Answering an online questionnaire. You will be able to do this while your child is completing their assessment. The questionnaire will take about 50 minutes to complete and asks about you, your family and your child's health and development.

Optional parts of AQUA at 6

The following parts of the study are optional. It is your decision whether you agree to these. Whatever your decision, it will not affect participation in the rest of the study.

- A 3D photo of your child's face and head is optional. 3D photos are taken in the same way as a standard digital photograph, but using 7 cameras at the same time. It will take about 5 minutes to set-up the equipment, but the photo itself will only take a few seconds. The photo will be taken by an experienced medical photographer at the 3D Imaging Centre at The Royal Children's Hospital. All up, taking a 3D photo will take no more than 20 minutes. This includes making a CD with the image for you to take home.
- A brain MRI scan is also optional. MRI scans are expensive and we are funded to do 150 scans. Selected children with parent's consent will have their scan taken at the Children's MRI Centre. We will be offering scans based on the availability of the MRI machine each week and on the number of children in each group. For example, we want to make sure we have scans from the same number of boys and girls. The scan will take about 45 minutes, but beforehand, the children will have a practice MRI in a 'pretend' scanner to become familiar with the procedure. The MRI scanner uses a very strong magnet to take clear pictures of the inside of the body. Unlike an X-ray or CT scan, a MRI scan involves no ionizing radiation and is safe, painless and non-invasive. Participants invited to the MRI scan will receive more detailed information on this aspect of the study.



- We will ask for you to allow us access to the results of the Australian Early Development Census if your child is in Prep in 2018. This is also just an option. Every three years since 2009, the Australian Government has undertaken a census of all children in their first year of full-time schooling. In 2018, teachers will again complete an Early Development Instrument, which is a series of specific questions, using their knowledge and observations of the children in their class. This information will provide us with another measure of how your child is settling into school.
- We would like to store, use and potentially share the information you and your child have provided as part of the AQUA study for future ethically approved research, under strict ethical controls and protocols. This would be research that is related to the AQUA study. For example another project might be looking at nutrition in pregnancy and children's health outcomes. Any data shared, including imaging, will not identify you, your child or your family. It will only be used for large research projects where lots of shared data from different sources is needed to answer important research questions.

Do we need to do anything before the **AQUA at 6** assessment visit?

The main thing is to make a booking to attend on a day and time that is convenient to you. We will send you written confirmation of your appointment, along with instructions on how to get there.

If you consent to the 3D facial photo and/or MRI brain scan, we will try to schedule these appointments on the same day. If you prefer, we can arrange another time for you to come back in the following two weeks.

We will remind you by text message twice; one week before and then a day or two before your scheduled appointment.

Can I claim travel and accommodation expenses to attend the **AQUA at 6** assessment visit?

We will help you with your travel costs by paying for your parking at the Royal Children's Hospital, giving you a refreshment voucher you can use at one of the hospital cafés and a \$30 Coles Myer voucher.

If you have to stay overnight to attend or you are travelling from interstate, we also help with travel costs and accommodation.



Do I get the results of my child's assessments?

We will give you a report of your child's cognitive assessment. The report will outline your child's performance in the tests we did. The report will include a telephone number so that we can help answer any questions you may have about the results. If your child is having problems or your family needs additional support, we can offer advice and referrals if needed.

If your child is taking part in the 3D photo, we will give you a copy of the image on a CD to take home.

Our MRI brain scans are designed for research purposes and not for helping to diagnose, treat or manage a particular medical condition. Therefore, we don't normally provide feedback. However, a specialised radiologist looks at each MRI to make sure there is nothing unusual in the scans. If your child is having the MRI brain scan and anything unexpected is found, we will contact you to talk about it.

Are there any benefits for my child and other people in the future?

You may find it helpful to know if your child's development is in the normal range or not. You can choose to send the report to your paediatrician or family doctor, or to your child's school.

We hope that the AQUA study will provide information on any possible association between low or occasional drinking in pregnancy and child development that will help doctors, midwives and mums-to-be.

How do I let you know that we want to take part?

You can phone **03 8341 6370** to ask questions, book an appointment or opt out. Or, you can wait for the **AQUA at 6** team to contact you in the coming weeks to ask you if you want to take part.

Do we have to take part?

No, it's up to you to decide if you and your child take part in **AQUA at 6**. Of course, we hope that as many families as possible take part to help answer our important research questions.

What do I consent to, and do I need to agree to everything?

When you come for your assessment, we will ask you to complete two copies of the consent form. One will be for you to keep and one is for the **AQUA at 6** team. The consent form will also have tick boxes for you to choose the optional items you are happy to agree to.



Are there any risks or inconveniences for me or my child?

Taking part in **AQUA at 6** should not cause you or your child any harm. All the assessments are safe for children and have been tested with many children. We will take plenty of breaks and if you or your child feel anxious about any activity, we will move on to the next activity or stop the assessment altogether.

We don't expect any of the questions in your questionnaire to cause distress, but you do not have to answer any questions you don't want to.

The main inconvenience is likely to be the time taken for travel and the assessment. We will try our best to find the most convenient time. We can help with travel and time costs for your visit.

Are we able to withdraw?

You can withdraw from **AQUA at 6** at any time without explanation, by telling a team member during the assessment visit. After the visit, you can withdraw by calling us on **03 8341 6370** or writing to us. You can withdraw from the **AQUA at 6** follow-up and still remain in the AQUA study. If you withdraw from any parts of the AQUA study, we will use any information already collected, unless you tell us not to.

How will information about me and my child be kept confidential?

We will collect and use personal and health information about you and your child for research purposes. Any information that we collect will be treated as confidential, and we can only disclose information with your permission except as required by law.

The following people may access information collected as part of this research project:

- the research team involved with this project
- the Royal Children's Hospital Human Research Ethics Committee.

The information will be re-identifiable. This means that we will remove your and your child's name and give the information a special code number. Only the research team can match your child's name to their code number, if it is necessary to do so.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access and correct the information we collect and store about you. Please contact us if you would like to access this information.

We will keep information collected as part of a research project for seven years after your child's 18th birthday, or for fifteen years after the study has been completed, whichever is later. After this time it will be destroyed.

Results from this study may be presented at conferences or published in medical journals. When we write or talk about the results of this project, information will be provided in such a way that your child cannot be identified.



Who do I contact if I have any questions or concerns?

If you want to contact a member of the **AQUA at 6** team, please call us
Telephone: **03 8341 6370** or
Email: **aquastudy@mcri.edu.au**.

If you have any concerns and/or complaints about the study, the way it is being conducted or your child's rights as a research participant, and would like to speak to someone independent of the study, please contact the Director of Research Development & Ethics at the Royal Children's Hospital by phone on **03 9345 5044**.

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Thank you again for taking the time to read this pamphlet. We hope you and your child will take part in **AQUA at 6**. If so, we hope you will both find it a rewarding experience.



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