the children's hospital at Westmead

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Parent Information Sheet (Children 7-12 years)

The neural basis and treatment of reading disability in children with neurofibromatosis type 1

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We would like you and your child to consider participating in a research study being conducted by the Institute for Neuroscience and Muscle Research, The Children's Hospital at Westmead.

What is the study about?
Neurofibromatosis type 1 (NF1) is a genetic condition affecting approximately 1 in 3,000 individuals. The most common complications associated with NF1 in children are cognitive and learning difficulties. The focus of this study is on reading in children with NF1. Many previous studies have identified an increased rate of reading disability in children with NF1, with the main area of difficulty sounding out unfamiliar words (known as phonological dyslexia). Although this phonological dyslexia occurs in up to 67% of children with NF1, no studies have reported on the effects of interventions on the reading ability of children with NF1. Furthermore, very little is known about which areas of the brain may underlie poor reading.

This study will be conducted in two parts. The aim of Part A will be to see whether a computer-based training program can improve reading skills of children with phonological dyslexia by teaching them about letter-sound relationships (phonics). Part B of the study will involve a magnetic resonance imaging (MRI) of your child's brain. You and your child can participate in one or both parts of the study. Participation in Part A does not obligate you to participate in Part B.

Who can participate in the study?
Children with NF1 who are aged between 7-12 years and have phonological dyslexia can participate in Part A of this study (phonics training program). We will determine whether your child has phonological dyslexia at an initial screening assessment. Children with NF1 aged 7-12 years can participate in Part B of this study (brain scan) whether they have phonological dyslexia or not. Your child may not be able to participate in this study due to the presence of certain medical conditions e.g., diagnosed head injury, brain tumours, epilepsy or hydrocephalus. We will ask you about the presence of these conditions before you give consent for your child to participate in the study. All children who participate in the study should also be fluent in English. As the training program is online children will also need a computer with internet access.

What will the study involve?
In Part A of this study, your child will complete a screening assessment to determine his/her eligibility for our study (Time 1). This will involve your child answering questions, solving problems/puzzles, completing reading, spelling and maths tasks. The complete assessment will last approximately 3 hours (excluding breaks) and will be conducted at The Children's Hospital at Westmead. Breaks will be provided as necessary and if preferred, the assessment can be spread across two days. In addition, you will be given a short questionnaire to complete regarding your child's behaviour (this will take approximately 10 minutes). To ensure that all reading tests are scored accurately we will take an audio recording of your child's responses. Only the co-ordinating investigator will have access to these recordings.

If your child satisfies the inclusion criteria you will be invited to participate in the training program. As part of the training study you will be required to return to the hospital 8 weeks after the initial screening assessment to repeat some of the cognitive testing (Time 2). This second visit will be to establish any practice effects of the cognitive tests. Your child will then begin the 8 week training program. The training is a computer-based, online program that involves your child completing activities at home for 30 mins per day, 5 days per week. The program requires your child to listen to verbal computer instructions and click on screen images (headphones will be provided). The program will automatically adjust to your child's progress and present additional practice when necessary. We will also request that you sit with your child while they complete the tasks to provide any assistance as necessary. The study investigators will monitor your child's progress by reviewing the activities they have completed. If they appear to be experiencing difficulties the study investigators will contact you by phone to provide assistance.

After 8 weeks of completing the training program you will need to return to the hospital where your child will repeat some of the cognitive tests (Time 3). Then, after a further 8 weeks we will ask your child to complete a final cognitive assessment to determine any lasting benefits of the training program. A table below summarises the visits involved in the study.

Outline of visits

	Beginning of study (Time 1)	**8 weeks - after no training (Time 2)**	**16 weeks – after training (Time 3)**	**24 weeks – after no training (Time 4)**
Cognitive assessment – (3 hours approx.)	**X**			
Brief cognitive assessment – (1 ½ hours approx.)		**X**	**X**	**X**

In Part B of this study, your child will undergo a brain scan (magnetic resonance image; MRI). MRI produces microscopic images of brain tissue so that its structure can be analysed by a computer. This is a very safe technique which does not use X-rays or any other form of radiation. The scan involves your child lying quietly on a table that moves in and out of a tunnel shaped scanning device for approximately 20 minutes while scanning takes place. The machine is roomier than the usual models but is still quite noisy. Your child may bring a CD to listen to while the test is performed (the machine is equipped with a CD player). If your child feels claustrophobic or becomes distressed at any time, we will stop the test.

Are there any benefits for my child participating in the study?
At present there has been no investigation into effective interventions for children with NF1 and reading difficulties. We hope that this study will help us determine whether a computer-based phonics training program can improve your child's reading and reading related skills (e.g. phonological awareness, spelling). In addition, following completion of the 24 week trial you will receive a written summary of your child's cognitive strengths and weaknesses and provided with recommendations for additional services/support as necessary. Following the completion of the study you will receive a summary of your child's results.

Are there any side-effects and risk associated with this study?
The tests used in this assessment are widely used by psychologists and researchers. Your child will be asked to do tasks that most children enjoy. Some of the tasks may be easy, while others may be more difficult. A psychologist with experience in assessing children will administer the tests and your child will be able to take breaks when he/she needs to. If your child becomes anxious or doesn't want to continue the assessment, we will stop the testing immediately. The phonics training program used in this study is a commercially available computer-based program that is used widely to promote reading development. Activities are presented in a game-like format so that they are interesting and fun for children.

The MRI scan does not involve any exposure to radiation. After the scan, your child is free to resume all normal activities. There are no side effects. There are no known risks associated with exposure to MRI. Metal implanted prostheses are a potential risk during the MRI due to strong magnetic fields, so all potential participants will be screened for the presence of such prior to the scan. If your child has had surgery for scoliosis and has had rods implanted, please advise us. In most cases, a MRI can still be performed. However, if there is any possible risk to your child, the MRI will not be performed but your child can still participate in Part A of the study.

Confidentiality
We will make sure that your child's information remains confidential and your child will not be individually identifiable. Your child will be assigned an ID number which will be used in all records of the assessment. All data will be collected and stored in a password-protected computer or locked filing cabinet and only the study investigators will be able to see it. The data will be kept for a minimum of 15 years and will then be destroyed.

Other information
Participation in this project is voluntary and if you decide not to take part or decide to withdraw at any time this will not otherwise affect your child's care at the Hospital.

If you have any questions about the study, please do not hesitate to discuss them with Mrs Shelley Arnold (Robertson) (02 9845 3057) or Dr Jonathan Payne (02 9845 3698).

This project has been approved by The Children's Hospital at Westmead Ethics Committee. If you have any concerns about the conduct of the study, please do not hesitate to contact the Research Ethics Manager, Secretary of the Ethics Committee (02 9845 3017) and quote approval number 11/CHW/28.

This Information Sheet is for you to keep. We will also give you a copy of the signed consent form.