

Title: FAB Trial - Fluoxetine for the treatment of autistic repetitive behaviours	
Institution	Royal Children's Hospital, Melbourne
Researchers	Dr Roshan Virasinghe Sue Reid Alex Ure Dr Catherine Marraffa Associate Professor Dinah Reddihough
Contact Details	03 9345 5898 roshan.virasinghe@rch.org.au
Outline of Research	<p>Children and adolescents with autism may display many forms of repetitive and restricted behaviors. These include the following: 1. Stereotypy is purposeless movement, such as hand flapping or body rocking. 2. Compulsive behaviors appear to follow certain rules that must be applied rigidly, such as arranging objects in a certain way. 3. Sameness or resistance to change is, for example, insisting that furniture not be moved, wearing the same clothes or shoes, eating the same food, or refusing to change activity. 4. Rituals and routines involve the performance of daily activities in the same way each time, such as routines around mealtime or bedtime. 5. Restricted behavior is limited in focus, interest, or range, such as preoccupation with a particular television program or character. 6. Self-injury includes actions that injure oneself, such as biting and head-banging. These behaviours can cause problems at home, at school, and interfere with your child's ability to learn and interact socially. Over the last decade the 'off label' use of fluoxetine and other selective serotonin reuptake inhibitors (SSRIs) for the treatment of repetitive behaviours in children with autism has become increasing common, both in Australia and overseas. However based on the current available literature, the efficacy of SSRIs for the treatment of repetitive behaviours and other symptom domains in autism is yet to be established. It is therefore of importance that high quality, controlled and reproducible studies are performed to address the efficacy and safety of SSRIs in children with autism. The aim of this project is to determine the efficacy and safety of Fluoxetine for the treatment of restricted, repetitive and stereotyped behaviours in children and adolescents with autism. Participants will be aged between 8 and 17 years, have a known diagnosis of an autism spectrum disorder, and have troublesome restricted, repetitive and stereotyped behaviours. The study will be a randomised double-blind placebo-controlled trial, with parallel group design. Subjects will be randomised into two groups (active and placebo). The duration of participation will be 16 weeks.</p>
Findings to date	N/A
Expected start and finish dates	Commenced 25/8/08. Expected date of completion 31/12/09.