



STUDY SYNOPSIS

FLUOXETINE FOR THE TREATMENT OF RESTRICTED, REPETITIVE AND STEREOTYPED BEHAVIOURS IN CHILDREN AND ADOLESCENTS WITH AUTISM:

A RANDOMIZED DOUBLE BLIND PLACEBO-CONTROLLED TRIAL

INVESTIGATORS

Assoc Professor Dinah Reddihough
Developmental Medicine
The Royal Children's Hospital
Email: dinah.reddihough@rch.org.au
Phone: 9345 5898
Fax: 9345 5871

Dr Catherine Marraffa
Developmental Medicine
Royal's Children's Hospital
Email: catherine.marraffa@rch.org.au
Phone: 9545 5898
Fax: 9345 5871

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Repetitive behaviours are common in the autistic spectrum disorders, and are broadly defined as repetitive and non-functional activities or interests that occur regularly and interfere with daily functioning at home, at school, and in social settings. Repetitive behaviours include repetitive motor phenomena (eg. stereotypies), repetitive speech and language, restricted and repetitive play, a narrow range of interests, overwhelming preoccupations, obsessions, routines and rituals, and resistance to change. These behaviours may be associated with high levels of anxiety and self-injury. They result in significant functional impairment for the affected individual and interfere with quality of life, as well as creating a significant burden for the families involved.

Over the last decade, the ‘off label’ use of Fluoxetine and other selective serotonin reuptake inhibitors (SSRIs) in children with autism has become increasingly 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 appropriate dosing for SSRIs in children with autism remains in question. ‘Behavioural activation’ may be a critical factor in drug tolerability, when SSRIs are used in higher doses. It is therefore also of importance to determine the optimal dosing for children in this group.

The aim of this project is to determine the efficacy and safety of low dose fluoxetine for the treatment of restricted, repetitive and stereotyped behaviours in children and adolescents with autism.

The study will be a randomised double-blind placebo-controlled trial, with parallel group design. The duration of treatment will be 16 weeks. The duration of participation in the trial will be 22 weeks. Participants will be aged between 8 and less than 18 years, have a known diagnosis of an autism spectrum disorder, and have troublesome restricted, repetitive and stereotyped behaviours.

If you would like further information regarding the study, or have any further questions, please contact:

Mr Steven Kloprogge
Clinical Trial Coordinator

Phone
(03) 9345 4561 (Monday – Wednesday)
(03) 93455898 (Thursday – Friday)

Email
steven.kloprogge@mcri.edu.au

Address
Developmental Disability Research
Murdoch Children’s Research Institute
The Royal Children’s Hospital
Flemington Road Parkville Victoria 3052