

# A prospective Longitudinal trial of the effect of Atomoxetine on cognitive, educational, behavioural, social and emotional wellbeing in students with Attention Deficit Hyperactivity Disorder

<b>Submission date</b> 02/11/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/11/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 20/11/2006	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

LP0349029

# Study information

## Scientific Title

## Acronym

LAADHD

## Study objectives

It is hypothesised that over a period of 26 weeks' administration of atomoxetine, students with Attention Deficit Hyperactivity Disorder (ADHD) will demonstrate:

1. Improvement in the cognitive functions of working memory, verbal ability and cognitive efficiency
2. Improved executive functioning capacity
3. Improvement in their educational achievements in reading, mathematics, spelling and written composition.
4. Improvement in their depression and anxiety ratings.
5. Improvement in their social skills and perceptions of the classroom learning environment.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The study has been approved by the Curtin University Human Research Ethics Committee, (Approval Ref No. 28/2005), and complies with all requirements of the Australian National Health and Medical Research Committee.

## Study design

Prospective longitudinal study, with a control group of children without ADHD, matched for age and gender and within the same school class as the children with ADHD

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Attention Deficit Hyperactivity Disorder

## Interventions

Administration of atomoxetine for 26 weeks.

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Atomoxetine

**Primary outcome(s)**

1. Cognitive functioning, working memory, verbal ability and cognitive efficiency
2. Executive functioning (teacher and parent ratings)
3. Educational achievement

**Key secondary outcome(s)**

1. Depression (child, parent, teacher ratings)
2. Anxiety (child and parent ratings)
3. Social skills (teacher and parent ratings)
4. Perceptions of learning environment (child ratings)

**Completion date**

01/11/2007

## **Eligibility**

**Key inclusion criteria**

1. Boys and girls aged seven to 15 years
2. Meet the Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) criteria for ADHD, as determined by the referring paediatrician or child psychiatrist
3. Participants are naive to atomoxetine medication

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

7 years

**Upper age limit**

15 years

**Sex**

All

**Key exclusion criteria**

1. A history of bipolar or psychotic disorder
2. Tourettes syndrome
3. Substance abuse
4. Serious medical illness
5. Intellectual disability (Intelligence Quotient [IQ] less than 70)
6. Pregnancy
7. Non compliance with research protocol

**Date of first enrolment**

01/11/2006

**Date of final enrolment**

01/11/2007

## **Locations**

**Countries of recruitment**

Australia

**Study participating centre**

Department of Education

Perth, WA

Australia

6845

## **Sponsor information**

**Organisation**

Australian Research Council (Australia)

**ROR**

<https://ror.org/05mmh0f86>

## **Funder(s)**

**Funder type**

Research council

**Funder Name**

Australian Research Council (ARC) linkage grant (ref LP0349029), which includes:

**Funder Name**

ARC funding (AUD 173,000)

**Funder Name**

West Australian Dept of Education (AUD 15,000)

**Funder Name**

Association of Independent School of Western Australia (AUD 15,000)

**Funder Name**

Westmead Children's Hospital Education Research Institute (AUD19,500)

**Funder Name**

Eli Lilly Australia Pty Ltd (AUD 45,000)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration