

# A double-blind, placebo-controlled trial of methylphenidate in children with hyperkinetic disorder and moderate-severe learning disabilities

<b>Submission date</b> 10/03/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 09/05/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/01/2014	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## 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

CT2004-1

# Study information

## Scientific Title

## Acronym

HSEN

## Study objectives

1. What is the efficacy of methylphenidate, under conditions of individual dose optimization, in reducing the symptoms of attention deficit hyperactivity disorder (ADHD) among children with moderate and severe learning disabilities?
2. What are the adverse effects profile associated with methylphenidate treatment amongst children with learning disabilities and which children are at greater risk of developing side effects?
3. What are the predictors of good versus poor responders to treatment? In particular:
  - a. Are those with severe as opposed to moderate learning disabilities less likely to show a good response?
  - b. Presence of autistic symptoms

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

South East Multicentre Research Ethics Committee: MREC 04/01/013

## Study design

Randomized controlled trial stratified for severity of learning disability (30-49 versus 50-69).

## Primary study design

Interventional

## Study type(s)

Treatment

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

Hyperkinetic disorder, mental retardation (intellectual disability)

## Interventions

180 children between ages 7 and 15 years with moderate-severe learning disability and hyperkinetic disorder will be invited to take part in a randomized double-blind trial of methylphenidate versus placebo lasting 16 weeks. Medication dosage for methylphenidate will be individually optimized, balancing reduction in hyperkinetic symptoms against side effects. Three dose levels of immediate release medication will be tried, corresponding to 0.5 mg/kg, 1.0 mg/kg and 1.5 mg/kg daily dose in three divided doses (with the three doses corresponding to 40% in the morning, 40% at lunchtime and 20% after school of the total daily dose). Selection of optimal dose will be based on adverse effects and behavioural response. Treatment response will be determined by comparing baseline behaviour with that at 16 weeks. At the end of the 16 weeks, children will be unblinded. Those receiving placebo will have the opportunity to commence active medication with the same dose titration method. Those receiving active

medication may continue in an open-label trial, with the possibility of an increase in dose up to 2.0 mg/kg if warranted based on adverse effects and behavioural response. The trial will end at 50 weeks post randomization. Primary outcome points are 16 and 50 weeks, with additional measures wherever possible at 8, 12, 26 and 38 weeks. Ascertainment of research subjects occurs via two arms: clinical referral and population screening.

Not part of treatment trial but interventions:

A behavioural manual (written by the team) is given to all families at the time of eligibility assessment.

Where children have sleep problems, their parents are given a manual on managing sleep problems (standard manual written by Paul Montgomery).

Where sleep problems are ongoing, children may be given melatonin, commencing with 4 mg dose and continuing in weekly 3 mg increments up to 8 mg.

### **Intervention Type**

Drug

### **Phase**

Not Specified

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

Methylphenidate

### **Primary outcome(s)**

Conners parent and teacher questionnaires, short form: ADHD and hyperactivity indices

### **Key secondary outcome(s)**

1. Adverse events (other behaviours questionnaire plus any others noted)
2. Aberrant behaviour questionnaire
3. Quality of Life (Cadfield)
4. Parental Report on Neuropsychiatric Symptoms (PONS)

### **Completion date**

31/05/2007

## **Eligibility**

### **Key inclusion criteria**

1. Diagnosis of International Statistical Classification of Diseases and Related Health Problems - tenth revision (ICD-10) hyperkinetic disorder
2. Full-scale IQ 30-69 or age equivalent estimate
3. Living in catchment area of one of the participating centres
4. Child in stable care situation
5. Child regularly attending school (more than 75% of last school term)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Child

**Sex**

All

**Key exclusion criteria**

1. Child currently in another trial of psychoactive medication
2. Household member with recent diagnosis of substance abuse
3. Severe limitation of child's mobility
4. Presence of a degenerative disorder
5. Medical conditions precluding methylphenidate as treatment of first choice, including:
  - a. Poorly controlled or uncontrolled epilepsy
  - b. Presence of tics or Tourette disorder
  - c. History of psychotic, bipolar or severe obsessive compulsive disorder
  - d. Child on neuroleptic medication (must be withdrawn for 2 months prior to trial assessment)
  - e. History of intolerance to stimulant medication
  - f. Child poses a significant risk of suicidal or homicidal behaviour
6. Another child in the family/household already enrolled in this study
7. Ongoing child protection concerns

**Date of first enrolment**

01/06/2004

**Date of final enrolment**

31/05/2007

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Professor of Child and Adolescent Psychiatry**

London

United Kingdom

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**Sponsor information****Organisation**

King's College London (UK)

ROR

<https://ror.org/0220mzb33>

## Funder(s)

### Funder type

Charity

### Funder Name

The Health Foundation

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/05/2013		Yes	No