

# Cost-effectiveness of the demands and capacities model-based treatment compared to the Lidcombe Programme of early stuttering intervention: a randomised trial (the Rotterdam Evaluation study of Stuttering Treatment in children- A Randomized Trial)

<b>Submission date</b> 05/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/07/2015	<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

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## Additional identifiers

**Protocol serial number**

N/A

## Study information

### Scientific Title

Cost-effectiveness of the demands and capacities model-based treatment compared to the Lidcombe Programme of early stuttering intervention: a randomised trial (the Rotterdam Evaluation study of Stuttering Treatment in children- A Randomized Trial)

### Acronym

RESTART

### Study objectives

The Lidcombe Programme for early stuttering intervention is more cost-effective than the Demands and Capacities Model-based treatment.

On 10/01/2012 the overall trial end date was changed from 30/07/2010 to 01/12/2011.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics board of the Erasmus University in Rotterdam (Medisch Ethische Toetsings Commissie [METC]), 10/05/2007, ref: MEC-2006-349

### Study design

Multicentre single-blinded randomised active-controlled parallel-group trial

### Primary study design

Interventional

### Study type(s)

Treatment

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

Stuttering pre-schoolers

### Interventions

Demands and Capacities Model based treatment versus Lidcombe Programme.

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome(s)

1. The percentage of recovered children at 18 months post randomisation
2. The costs for a recovered child

All primary outcome measures will be measured at 3, 6, 12 and 18 months post starting the therapy.

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

1. The frequency of stuttering outside the clinic at 18 months post randomisation
2. The Health Utility Index
3. Visual Analogue Scale (Euroqol VAS proxy)
4. Child Health Questionnaire
5. Children Behaviour Check List

All secondary outcome measures will be measured at 3, 6, 12 and 18 months post starting the therapy, except the Children Behavioural Check List, which will be measured at 18 months only.

### **Completion date**

01/12/2011

## **Eligibility**

### **Key inclusion criteria**

1. Aged 3.0 to 6.3 years
2. Frequency of stuttering at least 3%
3. Parent and one therapist agree the child stutters
4. Parent rating of stuttering severity on an 8-point scale of at least 2
5. Proficiency in Dutch for children and parents

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

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Lower age limit**

3 years

### **Upper age limit**

6.3 years

### **Sex**

All

### **Key exclusion criteria**

1. Onset of stuttering within 6 months before recruitment
2. Treatment for stuttering during the previous 12 months
3. Diagnosed language disorder
4. Neurological, emotional, cognitive, behavioural or autism spectrum disorder

**Date of first enrolment**

01/08/2007

**Date of final enrolment**

01/12/2011

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**Erasmus University**

Rotterdam

Netherlands

3000 DR

## **Sponsor information**

**Organisation**

Erasmus Medical Centre (The Netherlands)

**ROR**

<https://ror.org/018906e22>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Netherlands Organisation for Health Research and Development

**Alternative Name(s)**

Netherlands Organisation for Health Research and Development

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**  
Netherlands

## 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	28/07/2015		Yes	No