

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)

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/08/2007

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

Age group

Child

Lower age limit

3 Years

Upper age limit

6.3 Years

Sex

Both

Target number of participants

196

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)

Sponsor details

Department of Health Policy and Management

P.O. Box 1738

Rotterdam

Netherlands

3000 DR

Sponsor type

Hospital/treatment centre

Website

<http://www.erasmusmc.nl/content/englishindex.htm>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Results article	results	28/07/2015		Yes	No