Cost-effectiveness of the Demands and Capacities Model based treatment compared to the Lidcombe programme of early stuttering intervention: Randomised trial

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To evaluate the cost-effectiveness of the Demands and Capacities Model based treatment (Dutch standard) compared to the Lidcombe programme for early stuttering intervention.Follow-up: Long-term outcome, taking into account recent genetic findings.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46887

Source
ToetsingOnline

Brief title
Cost-effectiveness of DCM based treatment and LP for early stuttering

Condition

- Other condition

Synonym
stuttering

Health condition

spraakstoornis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW,DT Fonds

Intervention

Keyword: Cost-effectiveness, Genes, Randomised trial, Stuttering, Treatment

Outcome measures

Primary outcome

The percentage of recovered children at 18 months post randomisation, frequency of stuttering and severity ratings, Child Health Questionnaire, costs for a recovered child.

Follow-up measurement: idem but > 2;6 years later. Also, disease specific questionnaire will eb fillid in by the children (OASES).

Secondary outcome

Health Utility Index, Child Behaviour Check List

Follow-up measurment: idem, but > 2;6 years later. Also: the questioannaires with Child's versions (HUI-3, TAPQOL, EQ-VAS), will be filled in by the children themselves. Besides, genetic mutations related to stuttering will be investigated.

Study description

Background summary

Currently, treatment is provided to all pre-school stuttering children, to prevent stuttering becoming a chronic, handicapping condition in some of them. In the Netherlands, most children are treated with the Dutch standard, the DCM. Experienced clinicians spend about 9 sessions of treatment for each child in the Demands and Capacities based treatment. Recently, the Australian standard treatment, the Lidcombe Programme has been introduced in the Netherlands. The lidcombe Programma takes mostly at least about 18 sessions, so twice as much. But, the clinicail impression is that the results with the Lidcombe Programme are significanty better. Yet, about 50 clinicians have been trained to deliver treatment along the LP approach also. The difference in empirical support for LP and DCM suggests that in the long-term, LP might be more cost-effective than the current standard, DCM: the proportion of pre-school stuttering children that not only decrease their stuttering frequency but recover from stuttering after completion of the LP might be higher than for DCM, though, for higher costs. But, in the long term, for comparable costs. This study therefore explores the cost-effectiveness of the two treatments.
For the Follow-up measurement:
Long-term follow-up after stuttering treatment is essential for a comprehensive understanding of the treatment outcome. Furthermore, genes related to stuttering have been demonstrated recently (Kang et al, 2010). During the proposed clinical follow-up study, the involvement and clinical relevance of these (and possibly other) genes will be studied as well.

Study objective

To evaluate the cost-effectiveness of the Demands and Capacities Model based treatment (Dutch standard) compared to the Lidcombe programme for early stuttering intervention.
Follow-up: Long-term outcome, taking into account recent genetic findings.

Study design

A pragmatic, open plan, parallel group, randomised trial with blinded outcome assessment.

Intervention

1. Treatment based on the Demands & Capacities Model
2. Lidcombe Programme of early stuttering intervention.

Study burden and risks

Maximum of 8,5 hours for filling in questionaires and making audio-recordings at home by the parents.

Follow-up: additional 2,5 hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

age at recruitment 3-6 years, frequency of stuttering at least 3.3% Stuttering Like Disfluencies , type of Stuttering Like Disfluencies cf. Yairi & Ambrose (2005), and proficiency in Dutch for children and parents

Exclusion criteria

onset of stuttering in the six months before recruitment, treatment for stuttering during the previous 12 months, and diagnosed neurological, learning, emotional or behavioral disorder.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2007
Enrollment:	199
Type:	Actual

Ethics review

Approved WMO Date:	09-05-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-07-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-03-2016
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL16180.078.07