

Randomised controlled trial of the Lidcombe programme of early stuttering intervention

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Abstract

Objectives To evaluate the efficacy of the Lidcombe programme of early stuttering intervention by comparison to a control group.

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

Setting Two public speech clinics in New Zealand.

Participants Stuttering preschool children who presented to the speech clinics for treatment. Inclusion criteria were age 3-6 years and frequency of stuttering of at least 2% syllables stuttered. Exclusion criteria were onset of stuttering during the six months before recruitment and treatment for stuttering during the previous 12 months. 54 participants were randomised: 29 to the Lidcombe programme arm and 25 to the control arm. 12 of the participants were girls.

Intervention Lidcombe programme of early stuttering intervention.

Main outcome measures Frequency of stuttering was measured as the proportion of syllables stuttered, from audiotaped recordings of participants' conversational speech outside the clinic. Parents in both arms of the trial collected speech samples in three different speaking situations before randomisation and at three, six, and nine months after randomisation.

Results Analysis showed a highly significant difference ($P=0.003$) at nine months after randomisation. The mean proportion of syllables stuttered at nine months after randomisation was 1.5% (SD 1.4) for the treatment arm and 3.9% (SD 3.5) for the control arm, giving an effect size of 2.3% of syllables stuttered (95% confidence interval 0.8 to 3.9). This effect size was more than double the minimum clinically worthwhile difference specified in the trial protocol.

Conclusions The results provide evidence from a randomised controlled trial to support early intervention for stuttering. The Lidcombe programme is an efficacious treatment for stuttering in children of preschool age.

Introduction

Stuttering usually starts in the third and fourth years of life, after a period of apparently normal speech development. Around 5% of children begin to stutter.¹ Irre-

spective of the severity of stuttering,² the recovery rate without professional intervention is 74%,³ Girls are more likely to recover than boys, and children with a family history of recovery are more likely to recover than those without such a history. Stuttering should be treated in the preschool years, primarily because it becomes less tractable as children get older. Once stuttering becomes chronic, communication can be severely impaired, with devastating social, emotional, educational, and vocational effects.¹⁻⁵

Several treatments for early stuttering are currently available,⁶ but only one, the Lidcombe programme, has been studied with phase I and II clinical trials.⁷ This programme is a behavioural treatment developed specifically for stuttering in children of preschool age (younger than 6). It does not seem to change children's behaviour other than speech or affect the attachment of children and parents or use of language.⁸⁻⁹ We investigated the efficacy of the Lidcombe programme through comparison with a control group that received no formal treatment, in a pragmatic, open plan, parallel group, randomised controlled trial. The minimum worthwhile difference between the two arms was set at 1.0% of syllables stuttered.

Methods

The two treatment sites were in Christchurch and Auckland, New Zealand. The study population consisted of preschool children who presented to these speech clinics for treatment. Inclusion criteria for the trial were age at recruitment of 3-6 years, stuttering as diagnosed by using standard procedures,¹⁰ at least 2% of syllables stuttered, and proficiency in English for children and parents. Exclusion criteria were treatment for stuttering during the previous 12 months and onset of stuttering in the six months before recruitment.

Throughout the Lidcombe programme, parents provide verbal contingencies for periods of stutter free speech and for moments of stuttering. This occurs in conversational exchanges with the child in the child's natural environment (see bmj.com for details). The programme is conducted under the guidance of a speech pathologist. During the first stage of the programme, a parent conducts the treatment for

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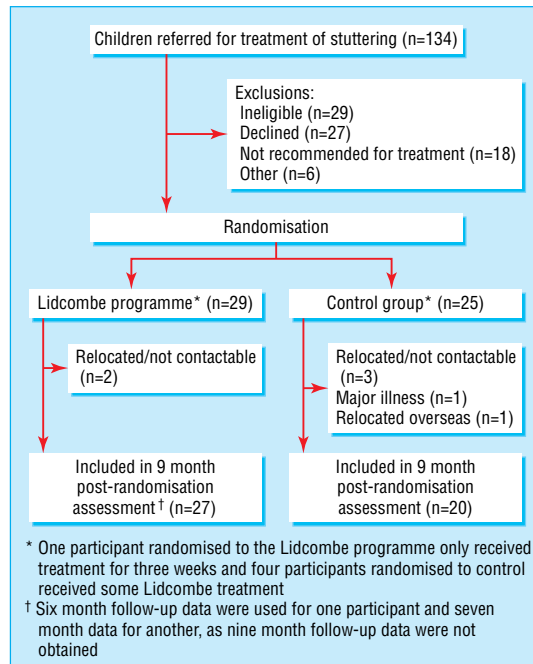
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Flow of participants through the trial

prescribed periods each day, and parent and child visit the speech pathologist once a week. The second stage starts when stuttering has been maintained a frequency of less than 1.0% of syllables stuttered over three consecutive weeks and is designed to maintain those low levels. Treatment is withdrawn, and the frequency of clinic visits decreases over a period of at least one year, providing stuttering remains at less than 1.0% of syllables stuttered. See bmj.com for details of treatment.

Compliance with treatment was established by the consulting clinicians who trained the parents in the procedures and with sample tape recordings of parents conducting the treatments with their children in everyday speaking environments. We asked parents in both arms of the trial to use audiotape recorders to collect three samples of their child's conversational speech outside the clinic, before randomisation and then three, six, and nine months after randomisation. Experienced speech pathology observers measured the proportion of syllables stuttered from each recording in real time. Intrajudge and interjudge reliability was assessed on a 5% sample of tape recordings from both sites.

The frequency of stuttering analysed for each child was an average of their nine month samples. All analyses were by intention to treat. We used the last observation carried forward for two participants without follow-up tapes at nine months.

Treatment assignment and blinding

Treatment assignment was conducted independently of the treating clinician (see bmj.com for details). Dynamically balanced randomisation¹¹ was used, with

stratification by age, sex, severity of stuttering, treatment site, and family history of recovery from stuttering. Because blinding was not possible, observers blinded to treatment allocation assessed outcomes.

Results

We were able to include and randomise only 54 participants, owing to difficulty with recruitment, between 1999 and 2003. Seven (13%) of the 54 randomised participants did not complete the trial, and data after randomisation were not available, with all analyses being performed on 47 participants. The figure shows the flow of participants through the trial. Participants who were lost to follow-up were similar to those remaining in the trial in severity, sex, treatment group assigned, or family history of recovery from stuttering (see bmj.com), but were on average nine months older ($P=0.015$, two sample *t* test). Two participants had data for analysis available for only six months and seven months, respectively, after randomisation. The median time from randomisation to final follow-up was 11 months in the control arm and nine months in the treatment arm. Five (9%) protocol violations occurred (see bmj.com). Three participants allocated to the control arm received other treatment.

Speech samples

For each child at each of the measurement occasions in the trial, an average of 2.3 (range 1-6) speech samples were available for analysis. The speech samples obtained had a mean duration of 433 syllables (SD 12). We obtained intraclass correlations of $r=0.99$ for both intrajudge and interjudge reliability.

Analysis

Of the 54 participants recruited to the study, 29 were allocated to the treatment group and 25 to the control group. Characteristics of the two groups before treatment were similar (see bmj.com), as was their severity of stuttering measured by proportion of syllables stuttered (table 1). At nine months after randomisation, we noted a difference of 2.3% of syllables stuttered between the treatment group and the control group (95% confidence interval 0.8% to 3.9%, $P=0.003$). The results were similar after adjustment for treatment site, baseline severity, age, sex, and family history of recovery from stuttering.

We conducted an exploratory analysis of the proportion of children with less than 1.0 % syllables stuttered at nine months after randomisation. The proportion was higher in the Lidcombe arm than in the control arm when adjusted for the baseline severity score in a logistic regression model (see bmj.com). The only test of heterogeneity to reach significance shows a larger effect of treatment for those children without a family history of recovery from stuttering than for children with a history. Effect sizes seemed to be consistent in all other important subgroups, with the possible exception of the treatment site.

Discussion

After nine months, the reduction of stuttering in the Lidcombe programme group was significantly and clinically greater than natural recovery. The estimated effect size of 2.3% of syllables stuttered is more than

Severity of stuttering (% syllables stuttered) before randomisation and at nine months. Values are means with standard deviations unless otherwise indicated

	Lidcombe programme (n=27)	Control (n=20)	Difference in % syllables stuttered at nine months (95% CI, P value)
Before randomisation	6.4 (4.3)	6.8 (4.9)	2.3 (0.8 to 3.9, P=0.003)
At nine months	1.5 (1.4)	3.9 (3.5)	

double the minimum clinically worthwhile difference specified in the trial protocol. At nine months, the control group had reduced their frequency of stuttering by an average of 43%, presumably from a combination of natural recovery and the ad hoc treatment given to some of the participants. However, only 15% of children in the control arm attained a minimal level of stuttering as defined in the trial protocol. In contrast, the treatment group had reduced their stuttering by 77%, resulting in a mean frequency of 1.5% syllables stuttered. Most children in the Lidcombe programme group were still in the second stage of the programme at the nine month follow-up point.

Study limitations

Our study has some limitations that should be acknowledged, but these are not sufficient to alter the main conclusion. The achieved sample size was only half that proposed, and seven of the 54 randomised participants did not complete the trial. These participants were older than the participants who did complete the trial, by an average of nine months. However, this difference in age is unlikely to have had an important effect on the results of the trial because the number of participants lost to follow-up is small, and there is no evidence to show that age is correlated with the proportion of syllables stuttered at nine months after randomisation for the participants who completed the trial.

Another limitation is that the post-randomisation period lasted nine months only. Ideally it should have been longer than this so that the children in the treatment group could have completed the second stage of the treatment programme and the children in the control group would have had more time to recover naturally. However, retaining a control group of stuttering children for longer than nine months is very difficult. Initially, follow-up was for 12 months, but this was reduced because parents of children allocated to the control group were unwilling to wait that long to receive treatment for their child.

Conclusions

Given its apparent efficacy, then, numerous reasons support implementing the Lidcombe programme in the preschool years. Although several children presenting at a clinic with early stuttering may recover without treatment, identifying these children in advance is not possible. Waiting for an extended period to see if natural recovery occurs is not acceptable because it seems that the Lidcombe programme is less efficacious once children move into the school age years.¹² In addition, delaying treatment until the school age years is not a viable option because of the negative social and cognitive consequences of stuttering at this age.¹³ If the disorder persists into the school age years a child is exposed to unacceptable risk of experiencing the disabling effects of chronic and intractable stuttering throughout life.

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What is already known on this topic

Chronic stuttering in adulthood is intractable and has serious disabling effects

The consensus is that early intervention in the preschool years is necessary

Randomised controlled trial evidence for the efficacy of early stuttering intervention has not been obtained

What this study adds

The Lidcombe programme, an early intervention for stuttering, is significantly and clinically more efficacious than no formal programme in treating stuttering in preschool children

Ethical approval: Ethical approval was obtained from the human ethics committees at the University of Sydney and University of Canterbury prior to conducting the study.

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