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In children with cleft palate speech disorder, is speech improved when trained and supported parents deliver the therapy compared with typical care?

Submission date
25/11/2019

Recruitment status
No longer recruiting

Registration date
12/12/2019

Overall study status
Completed

Last Edited
07/06/2023

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cleft palate is an opening in the roof of the mouth caused in early foetal development by tissues not joining properly. The opening can be repaired with surgery, but the unusual shape of the inside of the mouth can cause problems with the way children form sounds and develop speech. About 6 in every 10 children with repaired cleft palate have speech difficulties that require speech and language therapy in the preschool and/or school-aged years. Therapy early on can prevent long-term problems with communication, reading, learning and social skills. However, in these times of austerity and economic cutbacks, many children are on long waiting lists for therapy and often receive inadequate therapy. There is evidence to suggest parents can be helpful in promoting the early language and communication skills of children with cleft palate. The aim of this study was to find out if fully trained parents could undertake therapy to improve cleft-type speech disorders, supported by a specialist therapist in cleft palate and connected health, and how effective parent-led therapy is compared with typical therapy provided.

Who can participate?
Children aged 3 to 6.5 years, who have a cleft palate or other physical condition causing leakage of air from the soft palate that results in speech problems, and their parents

What does the study involve?
The child-parent pairs were randomly allocated to one of two groups. Those in the parent-led therapy group attended a 2-day training course, without their children, conducted by the two Chief Investigators/Specialist therapists. Parents were given an iPad, a detailed programme of activities and a diary for daily home practice for the first 6 weeks with all the therapy materials they would need. Parents undertook therapy sessions five times per week, for 10-15 minutes per day. The Chief Investigators/Specialist therapists reviewed the children with their parents at week 3 using FaceTime on the iPad. A face-to-face session took place at week 6. After this session, the therapist planned a further 6-week programme and a new detailed programme of activities, therapy materials and diary for daily home practice for the second 6 weeks was

provided. Again, the Chief Investigators/Specialist therapists reviewed the children with their parents at week 9 using FaceTime on the iPad. A face-to-face session took place at week 12 at the end of the therapy period.
Parents and children in the usual-therapy group attended six individual sessions with a non-specialist speech and language therapist (SLT) equivalent to that provided by local community speech therapy services. Parents observed the SLT sessions and parents undertook homework. At the end of the study, the Chief Investigators/Specialist therapists invited the parents to a 1-day parent-training course.
Children were seen five times during the study: at the beginning, immediately before therapy began, midway through the 12- week course, immediately following therapy and 2 months after the end of therapy.

What are the possible benefits and risks of participating?
The main potential benefit to participants was that this approach had the potential to empower parents in managing the health of their child. It allowed them to take more control on when and how to help their child to improve speech, and would be of benefit beyond the study as the parents could use their newly acquired skills in continued therapy if required. It may avoid the need for parental leave from work and reduce travel time and school interruption. Parents who completed this training and intervention may have increased their ease of understanding of their child's speech.
There were several potential risks of participating. The parent may fail to deliver the intervention properly or may unconsciously put too much pressure on the child and the child may become uncooperative in therapy. The parent may be overwhelmed by the additional responsibility and therefore the child may not receive sufficient or appropriate therapy. To address these two potential risks, the chief investigator of the study monitored progress at three weekly FaceTime sessions and problems were addressed by providing extra support or training. If this was not sufficient, the parent and child would have been withdrawn from the study and/or referred to the Local Speech and Language Therapist and the Cleft Team Speech and Language Therapist would be informed.
If the child's speech did not improve as expected with therapy, resulting in high parental anxiety, the chief investigator would refer the child back to the Cleft Team Speech and Language Therapist for further investigation as usual.
Problems with the iPad and/or FaceTime technology and/or connectivity were detected and resolved by the research team.
If the parent was unhappy being assigned to the standard care intervention group, this was discussed and if the parent wanted to attend parent training, they were offered a course at the end of the study.

Where is the study run from?
Great Ormond Street Hospital NHS Foundation Trust (UK) and Trinity College Dublin (Ireland)

When is the study starting and how long is it expected to run for?
April 2015 to May 2017

Who is funding the study?
CLEFT– Bridging the Gap (UK), the Cleft Lip and Palate Association of Ireland and the Temple Street Foundation (Ireland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
192488

Protocol serial number
14HS06, IRAS 192488

Study information

Scientific Title
In children with cleft palate speech disorder, is there a statistically significant difference in speech outcomes, activity and participation, when intervention is delivered by trained parents supported by connective health (PLAT), compared with routine care?
A comparative study of Parent Led, Therapist Supervised, Articulation Therapy (PLAT) versus routine speech therapy intervention for children with cleft palate speech disorders

Acronym
PLAT

Study objectives
The null hypothesis was that parent-led, therapist supervised, articulation therapy (PLAT) intervention achieves similar results to that of routine speech intervention undertaken by non-cleft specialist speech and language therapists (SLTs), where the child has speech difficulties associated with cleft palate/velopharyngeal dysfunction.

This study will further our understanding of therapy interventions which is lacking in the literature. If the outcome supports the hypothesis that PLAT compared well to local SLT services, it would provide evidence for parent delivered treatment. Potentially, it could provide a more efficient way of delivering therapy, ultimately reducing costs to the health service. This approach could then be implemented to improve SLT services for cleft children, helping address the problem of poor access to SLT. In the longer term, it is possible that this approach may also be of benefit in the Majority World where there is often very limited or no access to SLT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 20/10/2015, Our Lady's Children's Hospital Ethics (Medical Research) Committee (Cooley Rd, Crumlin, Dublin, D12 N512, Ireland; +353 1 409 6307; ethics.committee@olchc.ie), ref: GEN/446/15
2. Approved 29/10/2015, Children’s University Hospital (Temple Street, Dublin 1, Ireland; +353 1 892 1787; research@cuh.ie), ref: 15.054
3. Approved 03/11/2015, Research Ethics Committee, School of Linguistic, Speech and Communication Sciences Trinity College Dublin (The University of Dublin, Dublin 2, Ireland; +353 1 896 1560; clcsinfo@tcd.ie), ref: Sweeney 15/16
4. Approved 27/11/2015, London-Queen Square Research Ethics Committee (HRA NRES Centre Manchester, Barlow House, 3rd Floor, 4 Minshull Street, Manchester M1 3DZ; +44 (0)207 104 8345; NRESCommittee.London-QueenSquare@nhs.net), ref: 15/LO/1909

Study design
Unmasked randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Articulation difficulties in children born with cleft palate/velopharyngeal dysfunction

Interventions
This study aimed to investigate parent-led articulation therapy (PLAT) supported by a specialist therapist and connected health compared with typical routine care delivered by a non-specialist speech and language therapist (SLT). All cases were randomised using the Excel random function. Given the wide age range, parent-child dyads were stratified for age (≤4 years 6 months and >4 years 6 months) and randomised to either the PLAT or control group. The results of randomisation were transferred to a consecutive series of envelopes. Following consent /assent, the parent was handed the next consecutive sealed envelope for the age group of their child, containing details of the trial arm to which they had been randomised.

Parents allocated to the parent-trained group attended the 2-day training course, without their children, conducted by the two Cleft Specialist SLTs (CSLTs) in Dublin or London. Each parent borrowed an iPad for the duration of the study. The parent-training programme was delivered in different formats, including lectures, speech samples and quizzes. The programme included: custom-made videos of a therapist demonstrating and describing normal sound production, demonstrations of cleft speech errors and a selection of videos on how to elicit the consonant sounds of English, examples of video clips of their children demonstrating cleft speech characteristics; an overview of cleft lip and palate management; normal speech development; cleft palate speech characteristics; principles of speech therapy in cleft palate; the use of rewards, reinforcement, praise and motivation; factors associated with good and poor progress; practical aspects of therapy including how to set up therapy, for how long and when; managing siblings and inclusion of others in therapy; FaceTime set up and use on an iPad; quizzes to evaluate knowledge of sound production and therapy techniques. An overview of all of the resources, which were recommended for use by parents, was given including two articulation therapy apps and three game apps for use as rewards.
Following the training, each parent and child attended a 1-h individual session with a CSLT where speech sound targets for the intervention programme were identified. The CSLT designed a 6-week individualised therapy programme, which was emailed to the parents with a folder containing all the required therapy materials. They were asked to conduct therapy sessions 4/5 times per week, for 10-15 min per day for 12 weeks and to document the child's progress after each session. Parents had a FaceTime session using the iPad with the CSLT at weeks 3 and 9 for problem-solving, monitoring and adjusting the programme. A face-to-face session took place at week 6, following which the next 6-week programme was developed by the CSLT and materials assembled and emailed.

The standard intervention group attended six individual sessions with a non-cleft specialist Research Speech and Language Therapist (RSLT), who undertook 1 h of therapy every fortnight for 6 weeks, equivalent to that which is typically provided by local speech therapy services (Britton et al 2017). Parents observed the SLT sessions and were provided with weekly homework.

Children were assessedfive times during the study: at the beginning, immediately before therapy began, midway through the 12-week course, immediately following therapy and 2 months after the end of therapy.

Intervention Type
Behavioural

Primary outcome(s)
Extent of speech sound disorder assessed using Percent Consonant Correct - Revised scores. Single word naming, sentence repetition, sound stimulability and spontaneous speech were video recorded on five occasions: at baseline, immediately pre-intervention, midway through the intervention, immediately post-intervention and 2 months post-intervention. Consonants produced with correct place, manner and voice but with accompanying nasal emission /turbulence, dental/interdental, and weak/nasalized realizations were categorised as correct. PCC was calculated by the number of targets elicited divided by the number of targets correct, multiplied by 100. The targets analysed included a single target for each English consonant in word-initial and word-final position, except /h/ and /ŋ /, and the plosives, fricatives and affricates in word-initial and word-final position in the phrase/sentence samples. Two independent therapists, blinded to the treatment arm, completed the analysis.

Key secondary outcome(s))
1. Intelligibility of speech assessed using the Intelligibility in Context Scale (ICS) questionnaire at baseline and immediately after the end of the intervention
2. Real-world communication ability assessed using the Focus on Communication Outcomes for under Six (FOCUS) scale completed by the parent-trained group on day 1 of training and by the parents in the control group on day 1 of therapy and by all parents immediately after the end of the intervention

Completion date
01/05/2017

Eligibility

Key inclusion criteria
For children:
1. Aged between 3 and 6.5 years
2. Presenting with cleft palate with or without cleft lip at birth or velopharyngeal dysfunction, with or without a syndrome not associated with learning disability, with or without suspected velopharyngeal insufficiency
3. Presenting with at least one cleft speech characteristic, with or without developmental speech errors
4. Stimulable for at least one novel consonant
5. Has age-appropriate attention and listening skills, behaviour and receptive and expressive language levels
6. Fluent in English

For parents:
7. Fluent in English,
8. No diagnosed learning disability or mental health issues
9. Able to commit the time to undertake the intervention for 12 weeks

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group

Child

Lower age limit
3 years

Upper age limit
6.5 years

Sex
All

Total final enrolment
46

Key exclusion criteria
For children:
1. Has a syndrome with an associated learning disability
2. Has a known neurological deficit
3. Has behavioral problems
4. Has a bilateral hearing loss of greater than 30 decibels
5. Has a symptomatic fistula judged to affect articulation
6. Velopharyngeal surgery planned within the following 4 months
7. Presenting only with lateralisation/palatalisation or double articulation, or has no intra-oral air pressure on pressure consonants

For parents:
8. Known learning disability or mental health issues
9. Unable to make the time commitment

Date of first enrolment
29/01/2016

Date of final enrolment
13/09/2016

Locations

Countries of recruitment
United Kingdom

England

Ireland

Study participating centre
Great Ormond Street Hospital NHS Foundation Trust
Great Ormond Street

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Study participating centre
Trinity College Dublin
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Sponsor information

Organisation
Great Ormond Street Hospital for Children NHS Foundation Trust

Organisation
Trinity College Dublin

ROR
https://ror.org/02tyrky19

Funder(s)

Funder type
Charity

Funder Name
CLEFT- Bridging the Gap

Funder Name
Temple Street Foundation, Temple Street Children's University Hospital

Funder Name
Cleft Lip and Palate Association of Ireland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2020	20/08/2020	Yes	No
HRA research summary			28/06/2023	No	No