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Palin Stammering Therapy for School-aged Children: testing the methods for a full trial to compare the therapy with usual treatment

Submission date
10/12/2019

Recruitment status
No longer recruiting

Registration date
18/12/2019

Overall study status
Completed

Last Edited
14/02/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Stammering (otherwise known as stuttering) can have a long term impact on a child's development. This might include reduced self-esteem or increased anxiety, finding it harder to make friends and not participating in class. With approximately 66,000 school-aged children who stammer in England, there is a need to develop a therapy programme that is effective, cost-effective, and available to families through their local services. So far, there has been research into the effectiveness of therapy with young children and adults who stammer, but not into how to help school-aged children who stammer. The specialist team at the Michael Palin Centre for Stammering have developed a therapy programme for children aged 8-14 and their parents, called Palin Stammering Therapy for School Children (Palin STSC 8-14). Helping children to be more confident communicators is the main goal. To achieve this, the therapy focuses on three areas: building communication skills; finding ways to manage unhelpful thoughts and emotions; and, speech tools to reduce struggle when speaking. There is research to show that Palin STSC(8-14) helps families when it is delivered at the Michael Palin Centre. However, the researchers would like to find out whether the programme would be as helpful for children who stammer in other places too. In order to do this, they need to examine the effectiveness of Palin STSC(8-14) when compared to the usual treatment provided by other speech and language services. This would require a large-scale research trial. The current study therefore aims to determine the feasibility of conducting such a trial by exploring how many people can be recruited to participate and complete the study, how acceptable Palin STSC(8-14) is as a therapy for speech and language therapists, parents and children, and which assessments are needed to accurately demonstrate the effect of Palin STSC for children who stammer.

Who can participate?
Speech and language therapists who work with children who stammer aged 8-14 can take part. Children who stammer aged between 8-14 years, and who have at least one parent who can also take part in the study if their speech and language therapy service is involved.

What does the study involve?
Speech and language therapists who agree to take part are randomly allocated to either the

Palin STSC(8-14) therapy or 'Treatment as Usual'. If a therapist is allocated to Palin STSC(8-14) they attend a three-day training programme. When children are referred to participating speech and language therapy services, they are allocated to a speech and language therapist according to the service's normal procedures. Therapists allocated to the 'Treatment as Usual' provide the service that they usually would to any children that take part from their clinic and the therapists who have attended the Palin STSC(8-14) training provide that to families who consent to be part of the study. Therapists complete a number of questionnaires about their experience of being involved in the study at the start and at the end. They keep weekly records of all the therapy that takes place as part of the study. Parents and children also complete a range of questionnaires before they start therapy and six months later. Some of these can be completed online and others will be done in the clinic with a research assistant. Some of these questionnaires would be done even if the study was not taking place, while others are just for the research. The questionnaires are expected to take 80-90 minutes for each the child and parent. Children receiving Palin STSC(8-14) will complete an assessment and 10 weekly sessions of therapy which require at least one parent to be present. The therapy focuses on family communication skills, addressing thinking and emotional needs and speech strategies. Each session of Palin STSC is video recorded so that the research team can see how the therapy is being delivered. A few parents, children and therapists are asked to take part in telephone interviews before therapy, after therapy and 6 months after therapy started. The interviews provide an opportunity for participants to give feedback about their experience of being involved in the study.

What are the possible benefits and risks of participating?
Therapists who participate in the study will receive a free 3-day training course in Palin Stammering Therapy for School Children (Palin STSC), which includes a written therapy programme and training in the theory and methods of the approach. All therapists involved will learn about research methods and gain experience of being involved within a clinical trial. Although it is not known whether Palin STSC is more or less effective than usual treatment, parents and children involved in the study will not receive any less therapy than would otherwise be available to them. As each Speech and Language Therapy service provides different therapy and differing amounts of therapy, children may receive more therapy or a different therapy than would otherwise be available. The greatest risk to participants is that Palin STSC (8-14) will be ineffective or less effective than usual treatment. However, stammering is a chronic disorder which means there is no specific time frame in which therapy needs to be administered in order for it to be effective. As the study only requires a short time period of 6 months participation, families can seek alternative support once their participation is complete if they so wish. They are also free to withdraw from the trial at any time and access treatment as usual in their local service.

Where is the study run from?
The study is being run by the Michael Palin Centre for Stammering, which is part of Whittington Hospital NHS Trust. There are a number of Trusts who have consented to be involved:
1. Homerton University Hospital NHS Foundation Trust
2. North East London NHS Foundation Trust
3. PROVIDE

When is the study starting and how long is it expected to run for?
June 2019 to August 2022

Who is funding the study?
National Institute for Health Research (Research for Patient Benefit Programme) (UK)

Who is the main contact?
Dr Sharon Millard
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
251914

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
M-148-1255, IRAS 251914, CPMS 42224

Study information

Scientific Title
Evaluating Palin Stammering Therapy for School Children (Palin STSC 8-14) versus Treatment as Usual: a feasibility study

Acronym
Palin STSC (8-14)

Study objectives

This is a feasibility trial which specifically excludes hypothesis testing. Assessment of feasibility outcomes will inform whether progression to a full-scale trial is viable and will indicate any necessary adjustments (for example: changes to procedures, outcome measures, data collection methods, intervention delivery etc).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/07/2019, London Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, Barlow House 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; Tel: +44 (0)207 104 8063; Email: nrescommittee.london-bloomsbury@nhs.net), REC ref: 19/LO/0933

Study design
Two-arm feasibility cluster-randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stammering in children aged 8-14 years old

Interventions
Intervention:
Palin STSC (8-14) consists of:
- Comprehensive assessment of factors that are significant in relation to the child's stammering (based on current literature)
- 10 x 1 hour therapy sessions to take place once a week
- Review session taking place 6 months after the start of therapy to review progress and make further decisions regarding management

The therapy itself focuses on:
- Developing communication skills
- Exploring the cognitive/affective components of the disorder and strategies that will be helpful
- Identifying speech strategies that can enhance fluency and/or reduce struggle while speaking
- Helping parents to develop their knowledge and confidence in how to support their child

Control:
Treatment as usual:
There is no standard for treatment as usual and there are considerable differences across services. Treatment as usual might be school or clinic-based, individual of group, may or may not involve parents and may consist of any of the following, or combinations thereof:
- No service
- Termly/regular review
- Advice only
- Fluency enhancing techniques
- Confidence building

Speech and language therapists will be randomised into either the intervention or control arm using a computer randomisation programme.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment and attrition rates for speech and language therapists, children and parents. The numbers of children approached, numbers consenting and attrition rates will be recorded, as will evidence of non-consent or withdrawal, to determine whether sufficient numbers can be recruited (via NHS Trusts) and retained for a future trial, considering participation, dropout and completion rates. These records are monitored on a monthly basis by the research team (as a minimum) and reported to the STG every six months. The recruitment rates will be formally reviewed one year in to the study. If at least 25% of participants have been recruited at this point, the trial will continue.
2. The range, practicalities and completeness of the measures used to measure and predict response to treatment, measured using the degree of variability within the group and the change observed across each of the measures used, based on standard deviations and change. This will inform power calculations for the full trial and help determine whether the assessments included are appropriate or necessary in the full trial. This will be assessed once all data have been collected.
3. The acceptability of Palin STSC (8-14) to children, speech and language therapists and parents. This will be informed by recruitment and retention rates, number of sessions offered and attended, qualitative interviews and treatment fidelity data. The number of sessions offered and attended will be recorded in weekly 'session summaries' completed by the speech and language therapists. The interviews will take place prior to the start of therapy, at the end of therapy and 6 months following the start of therapy. Recruitment and retention rates will be recorded and monitored as described above.
4. The acceptability of the research methods, including randomisation and data collection. This will be informed by recruitment and retention rates, number of sessions offered and attended, qualitative interviews and treatment fidelity data. Recruitment and retention rates will be measured one year in to the study and as part of the final data analyses. The interviews will take place prior to the start of therapy, at the end of therapy and 6 months following the start of therapy. Attendance and adherence to the research protocols will be evaluated through weekly session records completed by the SLTs and evaluation of the pre-post questionnaire completion records on the database.
5. Treatment fidelity based on whether speech and language therapists implement Palin STSC (8-14) according to the therapy principles and methods taught. This will be measured using recorded video footage of the therapy sessions. Two recordings per child will be randomly selected and evaluated by a speech and language therapist who is experienced and expert in the approach and independent of the intervention delivery. A fidelity checklist based on the aspects of the program which are considered to be essential will be developed and informed by the treatment protocol to aid evaluation. At the end of each therapy session, speech and language therapists will also record the components of Palin STC that have been covered in a tick-box data collection sheet. The video recordings will be evaluated over a three-month period, after the last child participant has been recruited.
6. The feasibility of collecting health economic measures and of determining the cost-effectiveness of a full trial. The main purpose of the analysis will be to estimate completion rates and seek to identify big cost drivers, to inform the decision regarding how and what, cost and effect data would be collected within a more definitive study. In relation to costs, a parental /carer self-report questionnaire will be devised to monitor use of different services, including

NHS, personal social services (PSS) and education, as well as parental/carer time. Resource use associated with the therapist treatment will also be estimated. These questionnaires are completed by parents at the start and end of their involvement in the trial.

Key secondary outcome(s))
The secondary outcome measures will explore the variables that predict response to treatment. While they cannot be used to establish or predict outcome in this feasibility trial, completion of this battery of assessments will inform which assessments are required to predict outcome in the full trial study. The secondary outcome measures are:
1. Stammering frequency and severity, measured using a recorded sample of speech (reading and conversation) which will be analysed using the Stuttering Severity Instrument, child self-rating of satisfaction with communication, children's responses to the Speech Situation Checklists and the Behavioural Checklist. These will be completed at baseline and 6 months following the start of therapy. These data will be analysed when data collection is completed.
2. The impact of stammering on the child and parents, measured using the OASES-S, Communication Attitude Test and Palin Parent Rating Scales. These questionnaires are completed at baseline and 6 months following the start of therapy.
3. Children's classroom behaviours and peer relations, measured using the Strengths and Difficulties Questionnaire. This questionnaire is completed baseline and 6 months following the start of therapy.
4. The presence of anxiety or depression reaching a clinical threshold in children, measured using the Revised Children's anxiety and Depression Scale. These questionnaires will be completed at baseline and 6 months following the start of therapy.
5. Children's temperament, measured using the Early Adolescent Temperament Questionnaire-Revised or the Temperament in Middle Childhood Questionnaire, depending on the child's age. This will be completed at baseline.
6. Children's levels and use of language, measured by analysing a speech sample using the Child Language Exchange System. These speech sample recordings are made at baseline and 6 months following the start of therapy to determine stammering frequency and severity. These will be analysed to explore the children’s use determine the use of language.
7. Economic outcomes, measured using the Child Health Utility 9D, Quality of Life in a Child's Chronic Disease Questionnaire and bespoke resource use questionnaires to estimate therapist treatment costs, parent time and identify big cost drivers. These will be completed by parents at baseline and 6 months following the start of therapy.

Completion date
31/08/2022

Eligibility

Key inclusion criteria
There are three groups of participants in this study: speech and language therapists, children who stammer and parents of children who stammer. There are therefore three separate sets of inclusion criteria:

1. Speech and language therapists:
1.1. Not currently delivering Palin STSC (8-14) and not previously trained in the approach
1.2. Have the potential to identify and provide intervention (either Palin STSC (8-14) or Treatment as Usual) to at least 2 children and families within the duration of the study

2. Children who stammer:
2.1. Aged between 8 years 0 months and 14 years 11 months at the start of the study
2.2. Diagnosed/recognised as stammering by speech and language therapist, parent and self
2.3. Want to receive stammering therapy
2.4. Have at least one parent who is able to attend therapy and participate in the study

3. Parents of children who stammer:
3.1. Have a child who is participating in the study

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
104

Key exclusion criteria
1. Speech and language therapists:
1.1. Currently working with families on a weekly basis using principles of Palin STSC (8-14)
1.2. Unable to provide weekly family therapy sessions due to service of resource limitations

2. Children who stammer:
2.1. Have received therapy in the previous 6 months or are currently receiving speech and language therapy
2.2. Have attended the Michael Palin Centre for therapy
2.3. Do not have a parent who consents to take part in the study
2.4. Are involved in any other research study which involves an intervention or multiple assessments
2.5. Are accessing formal counselling through psychological services and the addition of Palin STSC is contra-indicated

3. Parents of children who stammer:
3.1. Their child has been excluded for any reason
3.2. There are any contra-indictions for therapy. This might include significant issues in the family that would mean that the therapy would cause additional burden, e.g. bereavement or birth of a baby

Date of first enrolment
18/07/2019

Date of final enrolment
03/12/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North East London Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
United Kingdom
RM13 8GQ

Study participating centre
Homerton University NHS Foundation Trust
Homerton Row
London
United Kingdom
E9 6SR

Study participating centre
Provide
900 The Crescent
Colchester Business Park
Colchester
United Kingdom
CO4 9YQ

Study participating centre
Black Country Healthcare NHS Foundation Trust
Research & Innovation
The Beeches
Penn Hospital
Penn Road
Wolverhampton
United Kingdom
WV4 5HN

Study participating centre
Kent Community Health NHS Foundation Trust
Trinity House
110-120 Upper Pemberton
Eureka Business Park
Ashford
United Kingdom
TN25 4AZ

Study participating centre
Lincolnshire Community Health Services
Beech House
Waterside South
Lincoln
United Kingdom
LN5 7JY

Study participating centre
Betsi Cadwaladr University Lhb
Executive Offices, Ysbyty Gwynedd
Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Study participating centre
Birmingham Community Healthcare NHS Foundation Trust
3 Priestley Wharf
Holt Street
Birmingham Science Park, Aston
Birmingham
United Kingdom
B7 4BN

Study participating centre
Cambridgeshire Community Services NHS Trust
Unit 7-8
Meadow Park
Meadow Lane
St. Ives
United Kingdom
PE27 4LG

Study participating centre
East Kent Hospitals University NHS Foundation Trust
Kent & Canterbury Hospital
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre
Lancashire & South Cumbria NHS Foundation Trust
Sceptre Point
Sceptre Way
Bamber Bridge
Preston
United Kingdom
PR5 6AW

Study participating centre
Leicestershire Partnership NHS Trust (university Hospitals)
George Hine House
Gipsy Lane
Humberstone
Leicester
United Kingdom
LE5 0TD

Study participating centre
Mid Cheshire Hospitals NHS Foundation Trust
Leighton Hospital
Leighton
Crewe
United Kingdom
CW1 4QJ

Study participating centre
Northern Care Alliance NHS Foundation Trust
Salford Royal
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Sussex Community NHS Foundation Trust
Brighton General Hospital
Elm Grove
Brighton
United Kingdom
BN2 3EW

Study participating centre
Wrightington, Wigan and Leigh NHS Foundation Trust
Wrightington Hospital
Hall Lane
Appley Bridge
Wigan
United Kingdom
WN6 9EP

Sponsor information

Organisation
Whittington Hospital NHS Trust (Noclor)

ROR
https://ror.org/02vg92y09

Funder(s)

Funder type
Not defined

Funder Name
National Institute for Health Research (Research for Patient Benefit)

Results and Publications

Individual participant data (IPD) sharing plan
Access to anonymised data will be available once the research team has analysed the data, the trial is complete and the findings have been reported. Post-trial, anonymised participant-level

dataset and statistical code for generating the results will be available on request. Requests for access should be made to the CI, Dr Sharon Millard (sharonmillard@nhs.net) and Sponsor, Whittington Hospital NHS Trust (sponsor.noclor@nhs.net). It would be anticipated that researchers or reviewers may seek consent to access the data. Requests will be reviewed on a case-by-case basis by the Chief Investigator and Co-Investigators or the Trial Steering Committee. Permission for secondary analysis will be considered by the research team and permission granted based on the applicant's CV, the appropriateness of the research question(s) and the intentions for dissemination. Since the study was not designed to compare outcomes for the treatment groups directly, requests for data to conduct such a comparison will not be approved. Due to the limits in participant consent, only anonymised data will be available, and video recorded data will not be available. The use of data is explicit on the Participant Information Sheets and within the GDPR statement. Throughout the study all participant data is pseudo anonymised, but for any external access, the data will be completely anonymised. Data is to be retained for 10 years.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes