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Palin Stuttering Therapy for School aged Children and usual treatment: A randomised controlled trial feasibility study

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ABSTRACT

Background: Despite a clear need for and evidence-based therapy for some children who stutter aged 8–14, there is no high-level evidence of effectiveness, with Speech and Language Therapists rating knowledge and confidence low. One programme which might address these needs, increase availability of services and improve outcomes, is Palin Stammering Therapy for School aged Children (Palin STSC(8−14)).
Aim: To investigate the feasibility of conducting a definitive randomised controlled trial comparing Palin STSC(8−14) with usual treatment. Objectives were to establish: recruitment and retention rates; appropriateness of the outcome measures; acceptability of the research and Palin STSC(8−14) therapy; treatment fidelity; and, appropriateness of the cost-effectiveness measures.
Method: A two-arm, cluster-randomised trial, with randomisation of therapists, stratified by service. Children aged 8;0–14;11, and their parent(s), were allocated to therapist and completed questionnaires pre-therapy and six months later. Assessments were selected for their potential to measure or predict therapy outcome. Therapists completed measures at the start and end of the trial. A process analysis was conducted, incorporating semi-structured interviews and treatment fidelity examination.
Results: Recruitment targets were exceeded (Children n = 67; SLTs n = 37). Research processes were largely acceptable, as was Palin STSC(8−14) therapy. Treatment fidelity was high, with SLT adherence at 85.7 % Mean number of sessions per child for Palin STSC(8−14) was 6.9 compared to 3.5 for usual treatment.
Conclusions: The feasibility targets were met. Based on recruitment, retention and adherence rates and our outcome measures, a full-scale randomised controlled trial appears feasible and warranted to assess the effectiveness of Palin STSC(8−14).

1. Introduction

Approximately 5–8 % of children will start to stutter, with a minority continuing to stutter into adolescence and adulthood (Yairi &

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Ambrose, 2013). Stuttering is characterised by repetitions of words, prolongations, blocking and repetition of sounds. These audible, overt characteristics may be accompanied by varying degrees of tension and struggle behaviours and are influenced by a range of linguistic, environmental, cognitive and affective factors. The life experiences of people who stutter are varied and variable (Erickson & Block, 2013), and not necessarily related to the frequency and severity of the overt stuttering (Eggers et al., 2022; Erikson & Block, 2013; Plexico & Erath, 2023).

Despite the clear need for therapy for some children, a national UK survey concluded that speech and language therapists are generally undecided about what therapy to use and believe that there are inadequate methods for working with people who stutter (Crichton-Smith et al., 2003). Compared to speech and language therapists specialising in stuttering, generalist therapists (i.e. those who manage a mixed caseload of children with speech, language and communication needs; and have minimal post graduate training in working with children who stutter), tended to be more pessimistic about outcomes, doubted their abilities and effectiveness, and expressed a need for additional training and support when working with this client group. This lack of knowledge and confidence, along with a lack of empirical evidence to inform clinical decision making (Baxter et al., 2015; Brignell et al., 2021; Hofslundsengen et al., 2022; Laiho et al., 2022), is likely to contribute to the "postcode lottery" for services across the UK (Action for Stammering Children, 2019; Bercow, 2018). In other words, children's access to services, the amount of therapy available and the content of that therapy is highly variable, undefined, and inconsistent. Children are often unable to access the support that they need. It depends on the service and the therapist available locally, and so is largely down to availability of resources and the geography of where the child lives (Action for Stammering Children, 2019).

1.1. *The impact of stuttering in the school years*

As the stuttering continues into the school years, it is likely to be long-term, and attitudes towards speech and communication become increasingly negative, with the ability to function in everyday speaking situations decreasing (Guttormsen et al., 2015). For children who stutter, stuttering can limit participation in conversations, lead to isolation and loneliness, reduce quality of life and impact on well-being, with elevated levels of anxiety reported compared to children who do not stutter (Bernard et al., 2022; Yaruss, 2010). A more negative experience of stuttering during the school years is associated with temperaments characterised by increased negative affect (higher levels of frustration, agression and depressive mood) and lower levels of surgency (more fearful/shy), with lower levels of resilience evident (Eggers et al., 2022; Walsh et al., 2023). Children who stutter are up to six times more likely to experience social anxiety, seven times more likely to have subclinical generalised anxiety (Iverach et al., 2016), and are more likely to experience sleep problems (Merlo & Briley, 2019), bullying, and be viewed more negatively than their fluent peers (Davis et al., 2002).

These issues can continue into adulthood, where stuttering is associated with high levels of social anxiety, depression, and suicidal ideation (Briley et al., 2021). Adults who stutter describe stuttering as affecting their job satisfaction and employment opportunities (Plexico et al., 2019), with those who stutter having lower status jobs, despite there being no difference in educational outcomes (McAllister et al., 2012).

Stuttering not only affects the child, but also impacts parents who experience feelings of helplessness, uncertainty, worry, fear, and guilt, with interactions and relationships between parents and child affected (Erickson & Block, 2013; Lau et al., 2012; Millard & Davis, 2016). Parents lack knowledge and confidence in how to support their child and experience anxiety about how they will cope both in the present and the future (Erickson & Block, 2013; Millard & Davis, 2016).

1.2. *The need for a comprehensive therapy approach*

Research exploring what parents and school-aged children want from therapy shows that needs are diverse (Berquez et al., 2015; Cooke & Millard, 2018; Millard & Davis, 2016). These studies show that, in addition to increased fluency and reduced struggle, children and their parents want to see improved functioning with regard to communication and participation. Children want to be able to be more independent, talk to teachers, put their hands up in class, answer more questions, give ideas, read aloud, join in conversations and make more friends (Berquez et al., 2015; Cooke & Millard, 2018). Parents express a desire to see their children talking more, taking more turns in conversations, socialising more, being less isolated and developing the skills they need to be able to deal with any teasing (Berquez et al., 2015). Both parents and children recognise the importance of a supportive environment. As part of their hopes for therapy, children and parents both wanted the parents to be more knowledgeable about stuttering and to know how to help and support the child (Berquez et al., 2015; Cooke & Millard, 2018; Millard & Davis, 2016), and children want others to understand what it is like for them to stutter (Cooke & Millard, 2018). Parents have also identified hopes for themselves, expressing hope that they will feel less anxious about the stuttering and less worried about their child's future (Millard & Davis, 2016).

This understanding of stuttering as a complex condition, along with knowledge that children and parents have a diversity of needs and hopes from therapy, suggests that therapy needs to be holistic and flexible. Therapies that focus on enhancing the factors that mitigate against and reduce stuttering impact, are more likely to yield the outcomes considered to be important by parents and children, rather than therapy directed towards increased fluency alone (Briley et al., 2022; Erickson & Block, 2013). Indeed, the pursuit of fluency as the primary goal in therapy is not only limited in scope and potential benefit for the client, fluency techniques themselves can compound the problem by reinforcing the need to pass as fluent, replacing stuttering with an 'effortful fluency' that is difficult to use and incongruent with the needs of the person (Douglass et al., 2019). Having the goal of 'not stuttering' is associated with increased avoidance of speaking, embarrassment, shame and physical struggle (Tichenor & Yaruss, 2019), further compounding the impact of stuttering. There is widespread, although not unanimous, agreement that a holistic approach which minimises the adverse impact of stuttering, alongside increased communication skills and reduced struggle speaking is best practice, as opposed to a single focus on fluency (Erickson & Block, 2013; Yaruss et al., 2012; Yaruss, 2010).

1.3. The evidence base for therapy with school aged children and adolescents

Four systematic reviews have reported no high-level evidence for interventions with school aged children or adolescents (Baxter et al., 2015; Brignell et al., 2021; Hofslundsengen et al., 2022; Laiho et al., 2022). No interventions for stuttering for school aged children have been assessed with an adequately powered, prospective, randomised controlled design. The quasi-experimental trials and reports of intervention outcome that do exist, focus on *speech restructuring* or *fluency enhancing* behavioural approaches to intervention, where stuttering frequency was the single outcome measure, a questionable primary outcome for the reasons already presented. The result of the paucity in research is that there is no standard intervention for children who stutter, no recommendations from the Royal College of Speech and Language Therapists regarding best practice and no NICE (National Institute for Health and Care Excellence) guidelines for assessment and therapy.

There is a clear need for a holistic and effective therapy for children who stutter. To maximise availability and access to those who need it, it will be important that the therapy can be taught to, learned, and implemented by, generalist Speech and Language Therapists/Pathologists (SLT/Ps).

1.4. Palin Stuttering Therapy for School Children aged 8–14 (Palin STSC(8−14))

Palin STSC(8−14) was developed by SLTs at the Michael Palin Centre for Stuttering in London. The team at this specialist centre has developed a number of therapy programmes for children who stutter, all of which include working with families and are based on the Palin Model (for more information, see: https://michaelpalincentreforstuttering.org/resources/for-slts/). This model is used to inform assessment and therapy across four areas: language and communication skills; cognitive and affective strengths and needs; speech motor skills; and, environmental support and influences. Descriptions of the approach to therapy with school aged children and examples of activities that are included in Palin STSC(8−14) are described by Caughter and colleagues (2022). Three preliminary studies have been conducted to establish initial effectiveness of the principles of this comprehensive therapy approach delivered in both group and individual family therapy contexts, in this specialist setting (Millard et al., 2014; Millard et al., 2017; Millard, 2011). The findings across the studies demonstrate that this approach can result in a reduction in stuttering frequency and a reduction in stuttering impact on the child (as measured by the Overall Assessment of the Speakers Experience of Stuttering (OASES; Yaruss & Quesal, 2016). Parental perceptions of change reflected those of the children, with parents also reporting a reduction in stuttering impact, along with reduced worry for them, and increased knowledge and confidence in managing the stuttering (as measured by the Palin Parent Rating Scales (Millard & Davis, 2016)). Importantly, the studies showed that improvements continued and were maintained over time (up to one year of monitoring post therapy).

While there are a number of papers that describe the principles of working and various elements of this therapy (e.g. Berquez & Kelman, 2018; Caughter & Crofts, 2018; Caughter et al., 2022), the approach is not formalised in a replicable format. To develop a replicable more formalised programme and specify the content of Palin STSC(8−14), an audit of two years of clinical records was carried out, to identify the number and content of therapy sessions delivered to children aged 8–14 and their parents. The result is a

Table 1
The goals of Palin STSC(8−14) therapy with examples of the topics and activities included.

Therapy goal	Topics	Examples of activities
Enhancing communication skills in the family	Building knowledge about the skills which are required for communication.	Parents and child watching a video of their interaction and identifying their own strengths and a target for development.
Increasing confidence and participation in speaking situations	Building knowledge and confidence in own communication skills. Attending to communication, rather than stuttering vs fluency. ‘Stretching comfort zones’ Openness about stuttering	Identifying communication strengths. Identifying what the child would like to do more of and what the first steps are to do that. Talking about stuttering, what it is, what it is like. Educating others about stuttering
Reducing child’s and parents’ worry about stuttering	Learning about stuttering, the factors that influence stuttering and the impact it has. Challenging myths and misconceptions about stuttering. Shifting focus of attention to positives rather than problems.	Talking about what stuttering is using the Palin Model and the iceberg analogy. Identifying strengths within those. Stuttering quiz. Watching videos of people talking about stuttering Reporting ‘what I have been pleased to notice’ each week.
Reducing stuttering and/or struggle speaking	Understanding what stuttering is, how struggle results from fighting the stutter, reducing avoidance. Considering which behaviours or thoughts are helpful or less helpful when speaking, and whether their advantages are short or long-term	Brainstorm: Advantages and disadvantages of being open about stuttering. Brainstorm: what do I do that helps me when I am getting stuck
Developing parents’ skills and confidence to support the child	Considering what the parents do already to support the child and how they might build on those skills now and for the future.	Encouraging parents and child to talk and negotiate responses to stuttering. Praise Problem solving

structured 10-week therapy programme, which consists of a series of topics and tasks which are intended to reduce the impact of the stutter on the child's ability to communicate. The programme requires training for the SLT/P, prior to implementation. The goals of the therapy, along with some examples of topics and activities which are included in the programme are listed in Table 1. It should be noted that these are examples from the programme, rather than an exhaustive list or complete session by session inventory.

1.5. The aim of this study

The ultimate goal is to conduct a full scale randomised controlled trial to compare the cost-effectiveness of Palin STSC(8−14) with usual National Health Service (NHS) treatment. Before a full trial can be undertaken, several questions regarding acceptability, participation and adherence with respect to both the research and the therapy programme by children, parents and speech and language therapists/pathologists, need to be addressed. This feasibility study aimed to assess the following objectives:

- Objective 1: to establish recruitment and attrition rates;
- Objective 2: to examine the suitability of the outcome measures. The outcome data will provide an indication of the degree of change expected, inform the power analyses and numbers required for the full study;
- Objective 3: to explore the acceptability of the intervention and research methods;
- Objective 4: to determine treatment fidelity for Palin STSC(8−14); and
- Objective 5: to assess the appropriateness of cost-effectiveness measures.

2. Method

2.1. Feasibility trial design

The study was a two-arm, cluster-randomised trial to investigate the feasibility of conducting a sufficiently powered trial to evaluate the effectiveness and cost-effectiveness of Palin STSC(8−14), compared with usual NHS treatment for children who stutter and their parents (Millard et al., 2022).

2.2. Setting

Speech and Language Therapists (SLTs) working in the NHS in England and Wales were recruited. All therapy took place in the local clinics and schools where the SLTs worked. As a result of the pandemic and the consequent changes in working practices, the protocol was altered to enable therapy to take place face-to-face or via a video platform, in either intervention arm.

2.3. Participants

There was no intention to develop an adequately powered study to explore differences between the outcomes of the two interventions. This was a pragmatic trial, with participant numbers informed by a previous UK study recruiting children who stutter receiving therapy from local SLTs (Roulstone & Hayhow, 2011) and in line with a powered randomised controlled trial (RCT) conducted with preschool children who stutter (Jones et al., 2005). The intention was to recruit enough participants to test the methods of the definitive trial and answer the objectives set.

There were four groups of participants:

2.4. Speech and Language Therapists

SLTs were approached through specialist professional organisations, through personal contacts, and, by targeting Trust managers and Research and Development departments. SLTs were eligible to participate if they had the potential to recruit and deliver therapy to a minimum of two children and had not been previously trained in Palin STSC(8−14). A target of 30 SLTs was set, based on recruitment to a previous UK study using similar recruitment methods (Roulstone & Hayhow, 2011).

2.5. Children who stutter

SLTs recruited to the study identified potential child participants from existing caseloads and new referrals. Children were eligible to participate if they: a) were aged between 8 years 0 months and 14 years 11 months when enrolled in the study; b) were identified as stuttering by a speech and language therapist, parent and self; c) wanted to receive stuttering therapy; d) had at least one parent who was able to attend therapy and participate in the study. Children were excluded if they: a) had received therapy in the previous 6 months, b) had attended the Michael Palin Centre for assessment or therapy; c) did not have a parent who consented to take part in the study; d) were involved in any other research study or therapy which would result in excess burden or contra-indicate Palin STSC (8−14).

We sought to recruit 60 children who stutter, along with one or both of their parents. It was intended therefore, that each SLT would provide therapy to two children in the trial.

2.6. *Parents of children who stutter*

Both parents of an eligible child (if involved in the child's day-to-day care) were invited to participate in the study. Parents could only participate if their child participated in the study. Parents, and therefore children, were excluded if parents highlighted any personal or family factors which would indicate that therapy or the timing of therapy was not appropriate. These decisions were made in consultation with the local SLT, as is typical when considering therapy.

2.7. *SLT managers*

In response to feedback from the SLTs, the original protocol was amended to recruit SLT managers who had management responsibility for the SLTs involved in the study and who had a role in the decision about whether the service would take part in the trial. They were invited to participate in semi structured interviews for the process evaluation. Due to the late introduction of this element to the trial, a target of 4–6 managers was set.

2.8. *Randomisation and allocation process*

Randomisation took place at the level of the SLT, using an online sequence generation service. SLTs were randomly allocated into one of the two treatment arms; Palin STSC(8−14) or Treatment as Usual (TAU), using blocked randomisation with a block length of 2, stratified by service. Parent-child dyads/triads were allocated to an SLT according to local service delivery models and informed of allocation on completion of the baseline assessments.

2.9. *Blinding*

Due to the nature of the therapy, children, parents and SLTs could not be blinded to the treatment arm to which they were allocated. Recruitment, data collection and study liaison was managed by three research assistants (two at any one time) for the period of the study. They were also responsible for the analysis of the speech samples. The baseline samples had to be scored and the data returned to the SLTs prior to the child's first clinic visit, so had to be assessed at the start of the study. These Research Assistants (RAs) were therefore not blind to the timings of the speech samples collected, nor the intervention group to which the child had been allocated. To reduce the risk of potential bias, and to test reliability, a random selection of 20 % of the speech samples were analysed by two of the RAs. The semi structured interviews were conducted by a RA who was known to the participants. The treatment fidelity aspect of the study was conducted by two additional RAs who had no previous contact with the participating SLTs.

2.9.1. *SLT training*

All SLTs received training on the research process and procedures. SLTs allocated to the TAU arm were instructed to provide their usual therapy and to keep records about the number and content of sessions provided. SLTs in the Palin STSC(8−14) arm also received training in the assessment and therapy methods. In order for the trial to reopen after the COVID-19 pandemic, this training was converted from a three-day face-to-face training programme into a package of 13 video recorded sessions (approximately 21 hours in total). In addition, SLTs were able to attend up to three live question and answer sessions with a specialist SLT of the programme. SLTs allocated to TAU were able to access Palin STSC(8−14) training at the end of the trial.

2.10. *Fidelity assessment*

SLTs delivering Palin STSC(8−14) video recorded each therapy session. The critical components of Palin STSC(8−14) were identified and agreed using a Delphi approach with a group of SLTs who were expert in the content and delivery of the therapy. The resulting checklist was used to evaluate a random sample of two therapy sessions from each child.

2.11. *Measures*

Basic demographic data including age, sex, and ethnicity were collected, alongside stuttering history information (time since onset, family history, previous therapy history). Postcodes of the participants were collected to determine the profile of the population with regard to income related deprivation. The Income Deprivation Affecting Children Index (IDACI, 2019) reports the proportion of all children aged 0–15 living in income deprived families within an area, with 1 being areas with the highest deprivation and 10 being the lowest. Deprivation indices are based on income, employment, education, health, access to services, crime and housing.

Measures were selected to evaluate the feasibility outcomes: to ascertain recruitment and retention, treatment fidelity, treatment outcome, acceptability of the research and therapy methods. Selected quantitative measures were chosen for their psychometric properties, contribution to clinical decision making, and potential value in evaluating outcome and the factors that may predict therapy outcomes in a definitive trial.

Some of the assessments completed are directly relevant for the implementation of therapy and the results of those were provided to the therapists for their clinical decision-making needs. The results of those provided to therapists in the Palin STSC(8−14) arm are marked * . Each therapist providing TAU was asked to identify at the start of the study any assessments that they used routinely. Where those overlapped with the trial assessment battery, results were shared with the SLT, to avoid families having to complete them twice.

Where permission was granted by publishers, these assessments were completed online, otherwise hard copies were posted. The online and postal questionnaires took each parent and child approximately 1.5 hours to complete and were completed at baseline and six months later (except the temperament questionnaires which were only completed at baseline).

2.11.1. Completed by children

- *Speech Sample* :* A reading and conversational speech sample was recorded and analysed by the RAs using the Stuttering Severity Instrument Fourth Edition (SSI-4) (Riley & Bakker, 2009).
- *Satisfaction with Communication:* In response to the question: "Considering everything that is to do with your stuttering, how satisfied are you with your ability to communicate in everyday speaking situations now?" children rated their satisfaction with communication between 1 (extremely satisfied) and 9 (extremely dissatisfied). This scale has been adapted from the Satisfaction with Communication in Everyday Speaking Situations scale which has been validated for adults (Karimi et al., 2018).

- *Behavior Assessment Battery* (Brutten & Vanryckeghem, 2007) evaluates the child's perspectives of communicating and stuttering and includes: Behavior Checklist (features of stuttering), Speech Situation Checklists (emotional reactions (SSC-ER) and speech disruption (SSC-SD) in different speaking situations) and Communication Attitude Test (CAT)* (speech-related belief system).
- *The Overall Assessment of the Speaker's Experience of Stuttering (OASES-S/T)** (Yaruss & Quesal, 2016) evaluates the impact of stuttering on an individual's life across four sections: general information; reactions to stuttering; communication in daily situations; and, quality of life. Children under age 13 completed the school age version (OASES-S) and those of 13 years old and above completed the teenager version (OASES-T).
- *Strengths and Difficulties Questionnaire (SDQ)* (Goodman, 2001): This is a screening tool for behavioural, emotional and social development with 5 subscales: emotional symptoms, conduct problems, hyperactivity/ inattention, peer relationship problems and pro-social behaviour. The Impact Supplement yields an Impact Score based on overall distress and impairment. Children aged 11–14 years completed the adolescent version (there is no self-rating version for those under 11 years of age). Scores are categorised into Close to Normal (reflecting scores from 80 % of the population); Slightly Raised/Lowered (reflecting scores from 10 % of the population); High/Low (scores from 5 % of the population); and, Very High/Very Low (scores from 5 % of the population). Impact scores range from 0 to 10.
- *Revised Children's Anxiety and Depression Scale (RCADS)* (Chorpita et al., 2000): This is a 47-item, youth self-report questionnaire with subscales comprising: separation anxiety disorder (SAD), social phobia (SP), generalized anxiety disorder (GAD), panic disorder (PD), obsessive compulsive disorder (OCD), and major depressive disorder (MDD). T Scores below 65 are within the normal range; between 65 and 69 are borderline (6 % of the population score in this range); and 70 + is the clinical range (2 % of the population score in this range).
- *Early Adolescent Temperament Questionnaire-Revised (EATQ-R)* (Ellis & Rothbart, 2001): Designed to explore temperament in 9–15 year olds to gain insight into positive and negative reactivity and regulation. Since temperament is considered to be stable over time (and therefore a change in ratings was not expected) and given the length of the assessment, the EATQ-R was completed at baseline only.
- *Child Health Utility-9 Dimensions (CHU-9D)* (Stevens, 2009): This is a series of 9 questions for the child to rate how they feel and their ability to participate in daily activities. The scores from this assessment enable a utility score to be estimated for the child, where a score of 0 is equal to death and 1 is full health (Stevens, 2012). Utility scores can in turn be converted into Quality Adjusted Life Years to be used in the health economic evaluation (Drummond et al., 2015).

2.11.2. Completed by parents

- *Palin Parent Rating Scales (Palin PRS)** (Millard & Davis, 2016): This standardised assessment consists of 19 rating scales and was completed by parents to measure their perspective across three factors: the impact of the stutter on the child; the severity of the stutter and the impact on the parents; parents' knowledge about stuttering and their confidence to support their child. Scores are categorised as: Very High; High; Medium; Low; Very Low.
- *Quality of Life in a Child's Chronic Disease Questionnaire (QLCCDQ)* (Farnik et al., 2010): The QLCCDQ consists of 15 questions covering 3 domains: child's symptoms, parental- emotions and roles limitation (subdomains: family, occupational and social roles functioning). Parents are asked to think about how they have been during the previous two weeks and to respond by circling an answer on a 7-point scale. The scale is based on description with commonly used expressions (for example "very often", "never"). The scale scoring is based on numbers (7 = not impaired at all - 1 = severely impaired), which allows the assessment of the total score as the mean of all 15 responses and the individual domain scores as the means of the items in those domains.
- *Strengths and Difficulties Questionnaire (SDQ)* (Goodman, 2001) parent version.
- *Revised Children's Anxiety and Depression Scale (RCADS)* (Chorpita et al., 2000) parent version.
- *Early Adolescent Temperament Questionnaire-Revised (EATQ-R)* (Ellis & Rothbart, 2001) completed by parents of those aged ≥9 years.
- *Temperament in Middle Childhood Questionnaire (TMCQ)* (Simonds, 2006) completed by parents of children aged 8 years.
- An amended (proxy) version of the *Child and Adolescent Service Use Schedule (CA-SUS)* (Byford et al., 1999). Information regarding use of resources, specifically as a result of the child's stutter, was collected, including the child's educational setting, any additional

educational support, health service contacts, and any specialist equipment or other extraordinary costs or extra care that has been provided.

2.11.3. Completed by SLTs

- *Confidence and knowledge about working with children who stutter:* A questionnaire was developed for the purposes of this study to explore therapists' knowledge and practices in working with school age children who stutter in the NHS. The SLTs rated their confidence in working with this client group at the start and end of the study. Those in the Palin STSC(8−14) treatment arm also completed this at the end of their training in the programme.
- *Session record form:* SLTs from both arms completed an online 'session summary checklist' following each therapy session to detail the logistical information (location, attendees, session number, length of time etc.) and therapeutic elements/topics covered. This provided data for the treatment fidelity evaluation, acceptability of the therapy methods and information about what constitutes TAU in these settings.

2.12. Data collection

Each parent and child completed the questionnaires at baseline and again approximately 6 months later (with the exception of the temperament questionnaires which were completed at baseline only). Study data were collected and managed using REDCap electronic data capture tools hosted at the University of East Anglia (Harris et al., 2009). Where postal questionnaires were used, data were manually uploaded into REDCap by the RAs.

2.13. Process evaluation

As recommended by the Medical Research Council guidance for RCTs (Moore et al., 2015), we included a qualitative process evaluation of the trial and the intervention. The aim was to identify the barriers and facilitators to taking part in the trial, as well as modifications that can be made to improve the experience of taking part in this research.

A purposive sample of 4 SLTs, 4 children and 4 parents from each treatment arm was recruited to take part in semi-structured qualitative interviews at the start and end of therapy, and at the end of the trial (total: 72 interviews). We sought to recruit children of different ages, from different services, with varying levels of stuttering impact, and parents with differing levels of knowledge and confidence. Therapists from different speech and language therapy services and from both Palin STSC(8−14) and Treatment as Usual groups were recruited.

During conversations with SLTs in their baseline interviews and in their training sessions, it became apparent that the support and attitudes of different managers varied and were crucial for successful participation, as well as influencing the SLT experience. We therefore amended the study to include interviews with managers. These were conducted at the start and end of a service being involved in the trial to identify the drivers that influenced decisions about whether a service or individual therapist could take part in the study and the amount of time they would be allocated to do so. Understanding the facilitators and obstacles from managers' perspectives will inform how managers are approached and the information that they receive in the full-scale trial.

2.14. Analysis

The primary statistical analysis was directed towards the aims and objectives of the feasibility study, particularly the values under Objective 1, including recruitment and attrition rates which were calculated with an appropriate 95 % confidence interval to inform the design of a future study.

Although not designed as an efficacy trial, estimations of treatment effect on the above-named efficacy variables were made, using linear models with appropriate link and error terms, with 95 % confidence intervals. Data from all participants as randomised in the trial were included in the 'intention to treat' analyses. To avoid attrition bias, outcome data from all participants were included regardless of protocol adherence.

For the process evaluation, all interviews were transcribed and analysed using constant comparisons from grounded theory methodology (Charmaz & Thornberg, 2021) to explore themes regarding process variables, fidelity and acceptability for both the therapy and the trial methods.

2.15. Health economics

Estimation of cost-effectiveness, within a health-technology assessment, is an iterative process (Sculpher et al., 1997). Levels of resource-use and quality of life (QoL) were monitored to inform the decision as to how costs and benefits can be measured as part of a future, more definitive study. Accordingly, completion rates for both the aforementioned CHU-9D (responses to the CHU-9D can be converted into QALY (Quality Adjusted Life Year) scores) and service use schedule (CA-SUS) are reported. Additionally, data from the training and completed session record forms were used to estimate SLT costs for both Palin STSC and TAU (at 2020/2021 price levels).

3. Results and discussion

The study was suspended during the COVID-19 pandemic for a total of 9 months. In order to reopen the trial, training and data collection processes had to be changed so they could be conducted online. Prior to the pandemic, training had been developed as a three day in-person group training workshop. This was changed into a series of online webinars that SLTs could access over a three-week period, with optional online ‘drop in’ question and answer sessions available. Originally, the following were completed in face-to-face sessions with an RA: participant consent forms; speech sample collection; paper versions of some child questionnaires. Following the pandemic, these were completed via a video platform. Removing the need for this face-to-face contact reduced travel time, costs and need for room facilities. These changes meant that geographical reach of the trial could be extended beyond the London region. Finally, due to the frequently changing situation, it was necessary for SLTs to be able to offer therapy remotely, which increased participation by children/parents and enabled the trial to continue during these unprecedented times. The protocol published by Millard et al. (2022) reflects those changes and the methods reported here. The impact that those changes had on the success of this trial was important and are reported here so that they are retained for the definitive trial.

3.1. Objective 1: recruitment and attrition rates

3.1.1. Sites and SLTs

Of the sites (n = 4) and SLTs (n = 15) that were recruited pre-pandemic, only one site was able to reopen, due to continued pandemic pressures, and 4 SLTs reconsented. The figures in Table 2 refer to SLTs’ recruitment (or re-recruited) post-pandemic, when the study was restarted. We recruited 37 SLTs from 14 sites (13 in England and 1 in Wales), mean 2.6 SLTs per site. Nineteen were allocated to Palin STSC(8−14) and 18 to TAU, with 16 and 14 respectively, recruiting children and parents who completed the baseline. One site, with 2 SLTs (one from each condition) had to withdraw before child recruitment began due to wider Trust pressures resulting from the pandemic. Recruitment of SLTs was closed ahead of the deadline when the target was exceeded, with some interested sites and SLTs unable to participate.

Baseline data were available for 50 SLTs recruited before and after the pandemic and these were used to explore the participant group willing to take part in a study of this type, as well as provide more information about what constitutes ‘treatment as usual in the NHS’ with regards to duration. Of these SLTs, 46 % (n = 23) considered themselves to be ‘specialists in stuttering’ and 54 % (n = 27) did not, with 44 % (n = 22) having received post-graduate training in stuttering. SLTs were asked how many children who stutter aged 8–14;11 were on their current caseload: Eight (16 %) had none; 16 (32 %) had 1–4; seven (14 %) had 5–8; seven (14 %) had 9–12; four (8 %) had 13–20; and, 8 (16 %) had 21 or more.

Table 2
Recruitment, attrition and attendance figures.

	Treatment As Usual	*Palin STSC*
Number of randomised child participants	24	32
Number of therapists who recruited children and parents who completed baseline (including those delivering zero therapy sessions)	14	16
Number of child participants per therapist (including those with zero sessions): mean (SD)	1.7 (0.47)	2.0 (0.82)
Number of sessions attended per child participant (including those with zero sessions): mean (SD)	3.5 (2.41)	6.9 (4.29)
Number of active therapists (delivering at least one session)[a]	13	15
Number of child participants attending at least one session[a]*: n (%)*	22 (91.7 %)	27 (84.4 %)
Number of child participants per active therapist[a]*: mean (SD)*	1.7 (0.48)	1.8 (0.94)
Total individual sessions attended[a]*: n (%)*		
Attended	83 (79.1 %)	220 (87.3 %)
Not attended[b]	22 (21.0 %)	32 (12.7 %)
Number of sessions attended per participant[a]*: mean (SD)*	3.8 (2.27)	8.1 (3.35)
Length of (participant attended) session in minutes[a]*: mean (SD)*	51.2 (22.9)	52.7 (14.1)
Missing	0	6
Number of withdrawals from study: n (%)	0	2 (6.3 %)
Child participant study withdrawal reason: n (%)		
Stammer no longer a concern	0	1 (50.0 %)
Change in family circumstance	0	1 (50.0 %)
Number of withdrawals from therapy[c]*: n (%)*	1 (4.2 %)	9 (28.1 %)
Number of participants completed study: n (%)	8 (33.3 %)	12 (37.5 %)

[a] Based on those active therapists and child participants (child participants attending at least one session). This does not include seven child participants (2 TAU, 5 PALIN STSC(8-14)) who contributed no session data at all (three withdrawals after baseline or prior to starting therapy, one participant with a therapist on long term sick and three participants who also had no sessions).

[b] Not attended is defined as when a specified (expected) appointment date has been logged as participant not attended

[c] Reasons given for withdrawing from therapy: Not wanting SLT input (TAU), Don’t like therapy (PALIN STSC), High distress levels during therapy (PALIN STSC), Referred to CAMHS as a priority for support (PALIN STSC), Difficulty with engagement/motivation (PALIN STSC), Stuttering no longer a concern (PALIN STSC x3), Stammering therapy not indicated at this time (PALIN STSC), Unable to attend sessions as change in circumstances (PALIN STSC)

3.1.2. Children and parents

The SLTs identified 88 parents of children who were willing to be contacted about the trial and to be screened for eligibility (see Fig. 1 for recruitment and retention figures). A total of 67 children and parents (76.1 %) consented to take part, with 56 (83 % of those

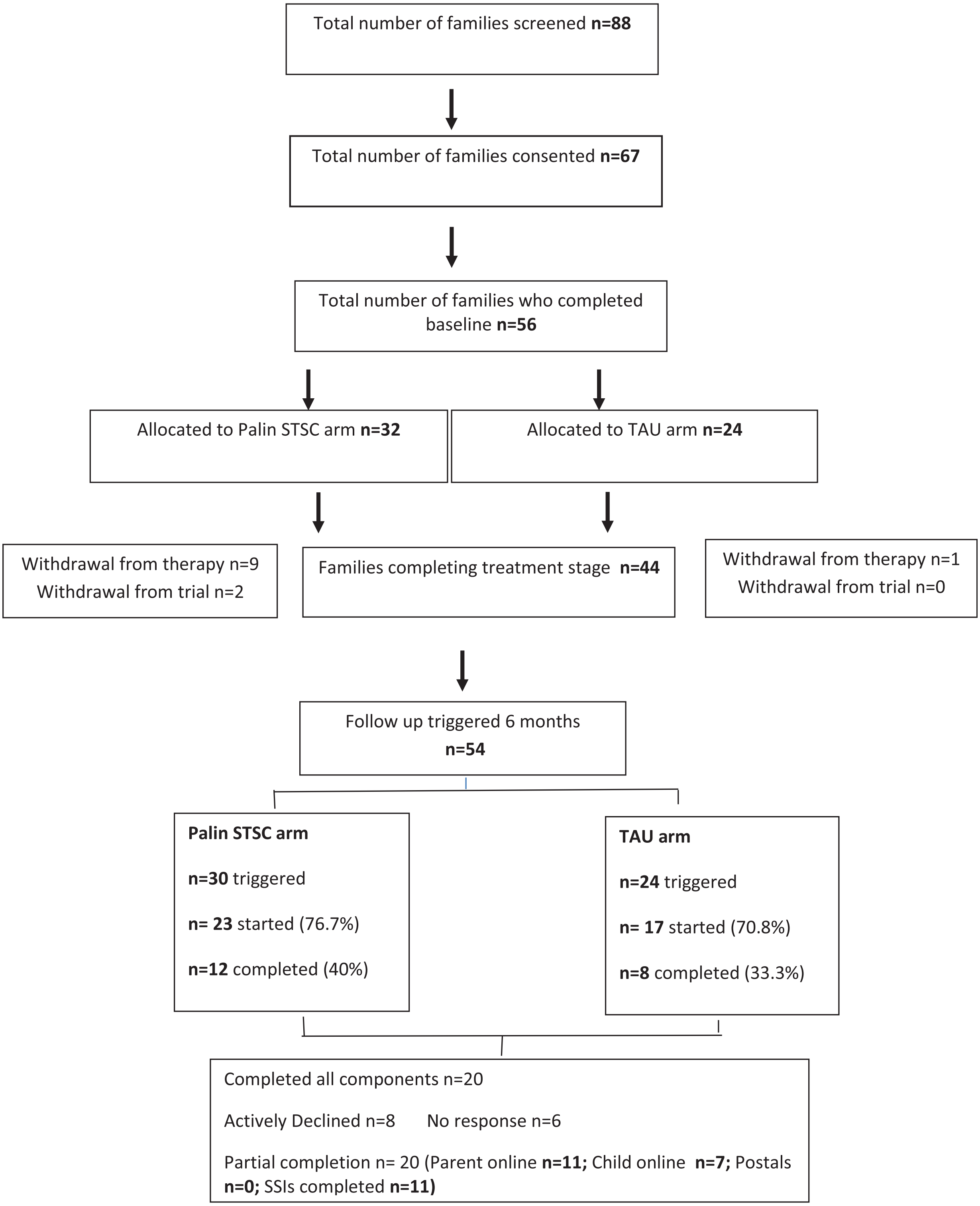

Fig. 1. Recruitment and attrition of child/parent participants.

consenting) completing the baseline assessments and allocated to an SLT for therapy.

There were 4 families who did not complete the baseline, for the following reasons: stuttering not a concern; familial issues that made taking part a burden; baseline questions felt intrusive, and, no reason given. Two families withdrew from the trial during the therapy phase, one because stuttering was no longer a concern and one because of a change in family circumstances. Of the 54 families remaining in the trial, 40 began the follow up assessments (59.7 % of those who originally consented, 72.7 % of those who completed baseline). Twenty dyads completed the follow up data collection in full and 20 began the process but did not complete all elements. The elements that were completed are reported in Fig. 1. Engagement and completion rates were higher in the Palin STSC(8−14) group than TAU (see Fig. 1).

The recruitment targets were exceeded for both SLTs and children indicating a willingness to take part. The ability to recruit and retain SLTs was particularly surprising and encouraging given the circumstances resulting from the pandemic, when services were depleted and under considerable strain. The changes to the protocol that were necessary because of the pandemic, proved to be advantageous for recruitment and participation and will be retained for a future trial.

The demographics of each group are reported in Table 3, with the two groups having similar sex ratios, ethnicity distributions and family history of stuttering. There were approximately four times as many boys as girls recruited, a ratio which reflects the incidence of persistent stuttering (Yairi & Ambrose, 2013). There was diversity amongst the recruited population regarding ethnicity. The proportion of participants identifying as Asian (10.7 %), Black (7.1 %), or Mixed. (5.4) ethnicity, compare favourably with the 2021 census statistics for England and Wales (9.3 %; 4 % and 2.9 % respectively). Since there is evidence that these populations are less likely to access health services or participate in research and the national statistics may not reflect the local populations participating in this study, these data should be monitored and compared to local population demographics in a full trial (Clarke et al., 2013). Postcodes were used to determine the levels of deprivation in the areas lived in by the study population (IDACI, 2019). Neighbourhoods falling within 10 % of the most deprived nationally are ranked 1, and 10 % least deprived neighbourhoods are ranked 10. Fig. 2 shows that children from areas within all ‘levels of deprivation’ were recruited, although it is evident that there was greater recruitment of those at the most extreme ends of the scale (i.e. areas of greatest deprivation and least deprivation).

3.2. *Objective 2: suitability of the outcome measures*

Child completed measures at baseline and six months later, along with treatment effect estimates are recorded in Table 4 and parent completed measures in Table 5. Data completion rates are reported in Fig. 1. Of all measures, postal questionnaires were least likely to be completed by the child. It is clear from the follow up data collection figures reported in Fig. 1 that there is a need to improve the completion rates by children. In order to achieve this for the definitive trial, the number of questionnaires will be reduced and shorter versions of assessments will be used where possible.

Scores at the start and end of the trial are recorded in Tables 4 and 5. The child completed measures show that at baseline, the severity of overt stuttering was mild, the impact (based on the OASES-S/T) was moderate (8–13 year olds) to moderate-severe (13–14;11 year olds). While the scores on the Behavior Assessment Battery (BCL, CAT, SSC-ER and SSC-SD) were not reported for each age (due to the small numbers), they were considerably higher than scores for children who do not stutter (Brutten & Vanryckeghem, 2007). Participants exhibited more negative attitudes to communication (CAT) and increased fear and difficulty with

Table 3
Child participant characteristics.

	Treatment As Usual (n = 24)	Palin STSC (n = 32)
Child sex at birth:		
Male	19 (79.2 %)	25 (78.1 %)
Female	5 (20.8 %)	7 (21.9 %)
Child age: mean (SD)	10.5 (2.25)	10.5 (1.87)
Child ethnicity:		
Asian – or Asian British - Indian	3 (12.5 %)	0
Asian – or Asian British - Pakistani	0	2 (6.3 %)
Any other Asian background	1 (4.2 %)	0
Black or Black British - Caribbean	2 (8.3 %)	2 (6.3 %)
Mixed – White and Black Caribbean	0	2 (6.3 %)
Mixed – White and Asian	0	1 (3.1 %)
White British	17 (70.8 %)	23 (71.9 %)
Any other White background	1 (4.2 %)	2 (6.3 %)
Parent relation to child:		
Mother	22 (91.7 %)	28 (87.5 %)
Father	1 (4.2 %)	4 (12.5 %)
Other	1 (4.2 %)	0
Parent stammered as a child:		
Yes	6 (25.0 %)	4 (12.5 %)
No	18 (75.0 %)	28 (87.5 %)
Parent stammers now:		
Yes	3 (12.5 %)	2 (6.3 %)
No	21 (87.5 %)	30 (93.8 %)

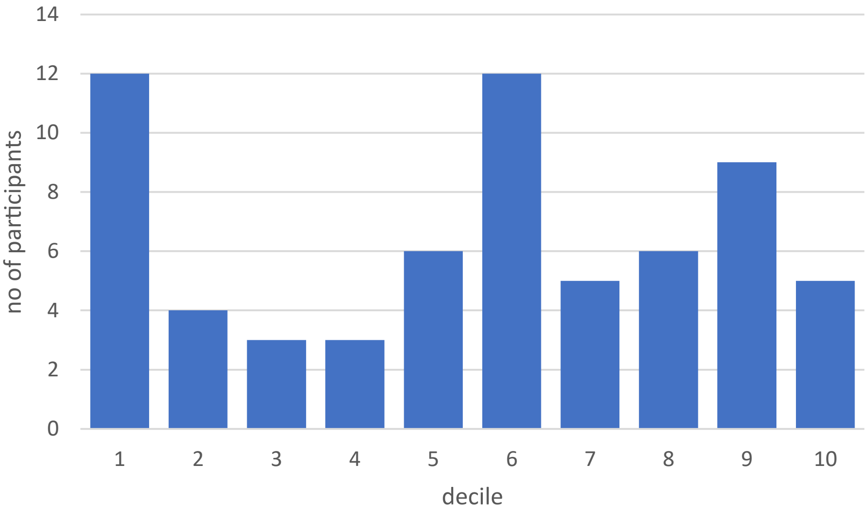

Fig. 2. The number of participants living in the most to least deprived post codes. Income deprivation affecting children - index 1 = 10 % most deprived postcodes to 10 = top 10 % least deprived postcodes.

speaking in a range of situations (SSC-ER and SSC-SD) than children who do not stutter. Mean scores on the RCADS (children and parent versions) indicated that anxiety was not at clinically concerning levels, although there were individuals for whom the scores reached these levels. The scores on the temperament questionnaires (EATQ-R parent and child versions) were lower than mean scores reported by Ellis (2002) for Surgency, Effortful Control and Affiliation, with mean scores for Negative Affect being higher. The EATQ-R scores are similar to those found by Eggers et al. (2022) in school aged children who stutter. As a cohort, these school aged children scored in the highest 10 % of the population with regard to Internalising Problems according to both child and parent ratings on the SDQ.

This study was not adequately powered to detect differences between groups or over time, indeed one purpose of the study is to determine how to power such an evaluation. To do this, it is important to explore the response to the intervention and the utility of the assessment measures. The results of the intention to treat analysis reported in Tables 4 and 5 show that over time there were improvements observed in both groups, with the exception of SSC-ER and SSC-SD which increased (worsened) in the TAU group. Although not statistically significant, there are some indications that the Palin STSC(8−14) group made greater gains in some areas, such as 'Satisfaction with Communication' and the impact of stuttering on the child (based on the OASES-S and Palin PRS Factor 1 ratings). The Project Advisory Group recommended that the primary outcome of a future trial should be the impact that the stuttering has, from the child's perspective and these results suggest that the measures employed here to do that are sensitive to change. There was a statistically significant difference in the Palin PRS Factor 3 scores over time, with greater gains in parental knowledge about stuttering and confidence in supporting their child, made by those who received Palin STSC(8−14). The scores and changes in ratings over time, support the use of these measures in evaluating the goals of Palin STSC(8−14).

3.2.1. *Reliability of the stuttering severity measure*

The severity of stuttering was calculated from the analysis of the recorded speech samples. To establish inter-rater reliability, 20 % of the speech samples were randomly selected and analysed by two research assistants, yielding an intra-class correlation co-efficient. 0.956, 95 % CI [0.919, 0.992], indicating excellent reliability.

3.3. *Objective 3: acceptability of the intervention and research methods*

No adverse effects were reported during the trial.

3.3.1. *Acceptability of Palin STSC(8−14) therapy*

- Concerns about the number of therapy sessions required for Palin STSC(8−14) were expressed by some SLTs, but the benefit was highlighted by others:

> *"I have to say that it's [Palin STSC(8−14)] a lot more than we currently offer in one go, so in terms of us as a service, it would be a big adjustment. But actually, from a therapy service point of view, we probably offer that many sessions, just across a much longer time-scale." (06 SLT).*
>
> *"I really like the STSC package because it just feels like it's brought everything together and they've given me something to do with that age group.…" (01 SLT).*

Table 4
Child completed measures at baseline and six months later. Mean and standard deviation scores.

Assessment	Treatment As Usual (N = 24[*])		Palin STSC (N = 32[*])		Treatment effect estimate
	Baseline	**6 month follow up**	**Baseline**	**6 month follow up**	
SSI−4	14.9 (8.23) Mild	15.5 (7.81) n = 14 Mild	15.0 (7.90) Mild	13.1 (8.31) n = 18 Mild	1.42 (−1.52, 4.36) p = 0.341
Satisfaction with Communication	5.0 (1.94)	4.0 (2.68) n = 11	5.1 (2.11)	2.6 (2.09) n = 16	1.32 (−0.63, 3.27) p = 0.072
Behavior Assessment Battery					
Behavior Checklist (BCL)	15.0 (9.24)	8.2 (11.04) n = 17	16.3 (8.81)	8.3 (9.86) n = 23	−0.17 (−6.78,6.44) p = 0.960
Communication Attitude Test (CAT)	15.8 (8.42)	7.5 (9.53) n = 17	19.3 (8.10)	6.1 (8.39) n = 23	2.01 (−3.58,7.61) p = 0.477
Speech Situation Checklist Emotional Reactions (SSC-ER)	106.6 (42.7) n = 22	116.3 (56.0) n = 10	126.0 (38.4) n = 29	99.0 (37.6) n = 9	12.1 (−15.6, 39.9) p = 0.367
Speech Situation Checklist Speech Disruption (SSC -SD)	104.0 (31.6) n = 23	115.0 (53.8) n = 10	138.5 (42.3) n = 31	114.5 (49.1) n = 11	10.8 (−33.3, 55.0) p = 0.612
OASES Total Score					
School (age 7–12) (OASES-S)	2.6 (0.54) n = 19 Moderate	2.3 (0.83) n = 9 Moderate	2.8 (0.62) n = 27 Moderate	2.1 (0.75) n = 11 Mild/Moderate	0.36 (−0.04,0.753) p = 0.087
Teen (age 13 – 17) OASES-T	3.0 (0.77) n = 5 Moderate/ Severe	2.7 (0.22) n = 2 Moderate	3.1 (0.49) n = 5 Moderate/ Severe	3.0 (0.68) n = 4 Moderate/ Severe	−0.88 (−1.77,0.024) p = 0.147
SDQ Scores[a]	n = 10	n = 5	n = 16	n = 7	
Conduct problems	1.5 (1.27)	1.4 (1.95)	2.3 (1.89)	2.0 (1.15)	−0.37 (−1.67,0.93) p = 0.534
Hyperactivity scale	4.1 (3.48)	3.8 (3.56)	4.9 (2.92)	4.3 (2.75)	−0.14 (−2.79,2.50) p = 0.904
Emotional problems	3.6 (2.07)	3.4 (2.51)	4.2 (2.17)	4.4 (2.70)	−0.22 (−2.04,1.61) p = 0.795
Peer relationships	3.1 (1.91) slightly raised	3.0 (2.24) Slightly raised	2.2 (3.02)	2.3 (2.98)	0.39 (−1.09,1.87) p = 0.565
Prosocial scale	6.4 (1.90) slightly low	7.2 (2.59)	7.8 (2.10)	8.0 (1.83)	0.27 (−2.11,2.65) p = 0.805
Externalising (Conduct problems + Hyperactivity score)	5.6 (4.20) slightly raised	5.2 (5.26)	7.2 (4.32) slightly raised	6.3 (3.54) slightly raised	−0.39 (−3.44,2.66) p = 0.780
Internalising (Emotional problems + Peer problems)	6.7 (3.65) slightly raised	6.4 (4.34) slightly raised	6.4 (4.18) slightly raised	6.7 (4.75) slightly raised	0.17 (−2.59,2.93) p = 0.892
Total Difficulties score	12.3 (5.58)	11.6 (7.33)	13.6 (7.94)	13.0 (8.25)	−0.11 (−5.01,4.78) p = 0.959
Impact Score	1.0 (1.25)	0.2 (0.45)	1.4 (2.26)	0.9 (1.86)	−0.18 (−2.36,2.00) p = 0.852
RCADS[b]	n = 23	n = 11	n = 32	n = 16	
Separation Anxiety	49.7 (11.54)	50.7 (12.59)	48.5 (8.17)	45.4 (11.24)	2.69 (−1.98,7.36) p = 0.245
Generalised Anxiety	41.9 (10.99)	39.0 (9.14)	40.3 (7.56)	41.2 (8.68)	−2.75 (−7.72,2.21) p = 0.264
Panic Disorder	42.8 (6.13)	45.9 (10.23)	42.7 (4.80)	45.3 (9.74)	−3.61 (−10.6,3.40) p = 0.297
Social Phobia	46.2 (14.23)	45.7 (10.23)	50.0 (10.83)	44.1 (12.7)	−0.01 (−8.97,8.94) p = 0.997
Obsessive-compulsive	35.2 (4.68)	39.0 (9.15)	37.8 (7.51)	40.2 (8.33)	−0.83 (−6.88,5.23) p = 0.780
Major Depression	41.3 (13.15)	43.6 (14.20)	41.9 (9.86)	44.4 (10.77)	−6.55 (−14.0,0.88) p = 0.081
EATQ-R	n = 17		n = 25		
Surgency	3.2 (0.50)		3.2 (0.49)		
Negative Affect	2.8 (0.80)		2.8 (0.56)		
Effortful Control	3.1 (0.66)		3.1 (0.67)		
Affiliation	3.2 (0.59)		3.3 (0.58)		
CHU−9D	0.863 (0.107)	n = 11 0.926 (0.082)	0.842 (0.088)	n = 16 0.890 (0.084)	−0.008 (−0.078, 0.062) p = 0.574

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[*] Participant number size for each assessment and time point, unless stated otherwise

[a] SDQ completed only by children aged $\geq$ 11. Scores fall within 80 % of the population unless otherwise indicated. ‘slightly raised / low’ reflects score in 10 % of the population.

[b] RCADS T scores reported; scores above 65 indicate clinically significant level of anxiety

Table 5
Parent completed measures at baseline and six months later. Mean and standard deviation scores.

	TAU n = 24		Palin STSC(8−14) n = 32		Treatment effect estimate
	Baseline Mean (SD)	Follow up Mean (SD)	Baseline Mean (SD)	Follow up Mean (SD)	
Palin PRS Scores		n = 13		N = 18	
Impact of stuttering on child	4.4 (1.34)	4.6 (1.81)	3.5 (1.20)	4.9 (1.56)	−0.80 (−1.72,0.11) p = 0.089
	Moderate	Moderate	High	Moderate	
Severity of Stuttering and Parent Concern	3.5 (0.99)	4.3 (0.98)	3.3 (1.22)	4.6 (1.61)	−0.26 (−1.06,0.53) p = 0.513
	Moderate	Low	High	Moderate	
Parent's Knowledge and Confidence	4.7 (1.49)	5.3 (1.49)	4.8 (1.25)	6.3 (1.02)	−1.02 (−1.80,−0.23) p = 0.015
	Moderate	Moderate	Moderate	Very High	*
SDQ Scores[1]	n = 21	n = 10	n = 30	n = 11	
Conduct problems	1.5 (1.41)	2.2 (2.49)	1.6 (1.79)	1.5 (1.13)	1.15 (−0.28, 2.57) p = 0.108
Hyperactivity scale	4.6 (2.59)	3.9 (3.44)	4.3 (2.71)	5.4 (2.66)	−1.11 (−2.68,0.46) p = 0.153
Emotional problems	2.5 (2.30)	2.7 (3.22)	3.3 (2.50)	2.3(2.53)	1.26 (−0.48,3.00) p = 0.145
Peer relationships	2.0 (2.62)	1.5 (2.16)	2.1 (2.40)	2.3 (2.53)	−0.66 (−2.19,0.88) p = 0.380
Prosocial scale	7.7 (2.50)	7.9 (2.62)	8.5 (1.22)	8.4 (1.59)	0.38 (−1.25,2.02) p = 0.632
Externalising (Conduct problems + Hyperactivity score)	6.1 (3.80)	6.2(5.47)	5.9 (3.95)	6.9 (3.00)	0.04 (−2.63,2.71) p = 0974
Internalising (Emotional problems + Peer problems)	4.5 (4.10)	4.3 (5.08)	5.4 (4.06)	4.5 (4.89)	0.73 (−1.83,3.30) p = 0.557
	Slightly raised	Slightly raised	Slightly raised	Slightly raised	
Total Difficulties score	10.7 (6.39)	10.5 (9.80)	11.3 (7.17)	11.5 (7.19)	0.93 (−3.66,5.52) p = 0.676
Impact Score	2.2 (5.95)	0.8 (2.20)	1.3 (2.03)	0.7 (1.56)	−0.14 (−2.14,1.86) p = 0.884
	A great deal	Only a little	A medium amount	Only a little	
Revised Children's Anxiety and Depression Scale[2]		n = 13		n = 19	
Separation Anxiety	49.7 (11.54)	47.1 (12.06)	48.5 (8.17)	48.7 (13.02)	−0.79 (−2.87,1.30) p = 0.458
Generalised Anxiety	41.9 (10.99)	38.8 (8.37)	40.3 (7.56)	39.8 (8.72)	−1.11 (−5.53,3.31) p = 0.613
Panic Disorder	42.8 (6.13)	43.2 (8.2)	42.7 (4.80)	43.1 (6.27)	−0.50 (−4.96,3.96) p = 0.819
Social Phobia	46.2 (14.23)	45.9 (12.39)	50.0 (10.83)	46.6 (14.04)	2.02 (−4.58,8.63) p = 0.536
Obsessive-Compulsive	35.2 (4.68)	35.7 (6.83)	37.8 (7.51)	36.1 (6.66)	1.04 (−2.50,4.58) p = 0.552
Major Depression	41.3 (13.15)	38.3 (11.80)	41.9 (9.86)	42.7 (10.31)	−4.41 (−10.8,1.94) p = 0.166
EATQ-R[3]	n = 17		N = 25		
Surgency	3.3 (0.69)		3.2 (0.53)		
Negative Affect	2.7 (0.77)		2.6 (0.14)		
Effort Control	2.9 (0.52)		2.9 (0.36)		
CBQ[4]	n = 7		n = 7		
Surgency	3.6 (0.69)		3.4 (0.83)		
Negative Affect	2.9 (0.70)		3.1 (0.56)		
Effort Control	3.1 (0.52)		3.1 (0.41)		
Quality of Life in a Child's Chronic Disease		n = 12		n = 19	
Family	6.8 (0.50)	6.54 (1.30)	6.6 (0.90)	6.76 (0.92)	−0.19 (−1.04,0.66) p = 0.644
Social	6.5 (0.70)	6.27 (1.36)	6.1 (0.82)	6.36 (0.95)	−0.29 (−1.02,0.45) p = 0.429
Occupational	6.8 (0.35)	6.53 (1.21)	6.6 (0.81)	6.81 (0.76)	−0.33 (−0.99,0.34) p = 0.319
Emotional	6.5 (0.42)	5.89 (1.67)	6.1 (0.73)	5.65 (1.23)	−0.57 (−1.64,0.49) p = 0.280
Symptoms	6.2 (0.84)	5.89 (1.79)	5.1 (1.32)	5.96 (1.09)	−0.16 (−1.24,0.92) p = 0.766
Role Limitations	5.8 (0.97)	6.28 (1.26)	5.3 (1.29)	6.35 (0.86)	−0.32 (−1.00,0.33) p = 0.335
Total	6.3 (0.47)	6.17 (1.36)	5.9 (0.78)	6.23 (0.84)	−0.46 (−1.23,0.32) p = 0.236

* significant $p < .05$

[1] Scores fall within 80 % of the population unless otherwise indicated. 'slightly raised / low' reflects score in 10 % of the population.

[2] RCADS T scores reported; scores above 65 indicate clinically significant level of anxiety

[3] Completed by parents of children aged ≥ 9 years

[4] Completed by parents of children < 9 years.

- Benefits of Palin STSC(8−14) were reported by children, parents and SLTs:

  "I'm so much more comfortable speaking out" (10, child).

  "She's very, very, very confident now…She's a now more open person. I think she's happier with herself now" (09 parent),

  "pretty much achieved every single goal and then surpassed her expectations of herself" (03 SLT).

- For some parents, the aims of the therapy were unclear and the lack of focus on reducing overt stuttering remained a concern:

  "I think maybe just more activities, I guess like to help with his fluency. I thought it was going to be a bit more, I don't know, like saying how to say different words, like maybe talking the words out" (23 parent).

3.3.2. SLT knowledge and confidence to work with school aged children who stutter

SLTs rated their knowledge about working with children who stutter aged 8–14 on a five-point Likert scale (1–5, with higher scores being more positive), at the start and end of the trial. Comparison of knowledge levels at the start [TAU:$\overline{X}$ = 3.7 (0.62); Palin STSC $\overline{X}$= 3.4 (0.71)] and end of the trial [TAU:$\overline{X}$ = 4.1 (0.56); Palin STSC: $\overline{X}$= 4.3 (0.54)] demonstrated a significant treatment effect, with those who had received Palin STSC(8−14) training showing significantly greater gains in knowledge [-0.42 (-0.81, −0.03) p = 0.034]. Using the same scale, SLTs also rated their confidence to work with this client group at the start [TAU:$\overline{X}$= 3.3 (0.67); Palin STSC: X = 3.0 (0.83)] and end [TAU:$\overline{X}$= 3.8 (0.54); Palin STSC $\overline{X}$= 4.0 (0.51)] of the trial. Again, there was a significant treatment effect, with those who had received Palin STSC(8−14) training showing significantly greater gains in confidence [-0.47 (-0.84, −0.11) p = 0.013] in working with this client group.

3.3.3. Acceptability of the research methods

Overall, the research methods, including the allocation to therapy arm were acceptable to both SLTs and the families. The process analysis provided greater insight into the variability of experiences and areas that can be barriers or facilitators to recruitment and attrition.

- Some SLTs found the time involved in the study to be a challenge in the initial stages (setting up the study and completing the training), with others suggesting that the ongoing recording processes were similar to the usual requirements in the NHS:

  “It’s just time really. I feel like for me, if I don’t do the Red Cap (session records) bit immediately, then it feels like quite a chore” (03 SLT).

  "once beginning phases were out the way, I felt like it’s all ticked along, quite nicely, and it’s just been perfectly manageable" (06 SLT).

  “I just copy and paste the bits from our notes that were relevant for the checklist, so it wasn’t too much extra work" (07 SLT).

- Some SLTs felt that the research had an impact on the service received by those taking part in the study in a negative way:

  "they’re starting treatment later than we expected. And actually, in that way, those families have waited longer than they would have otherwise" (27 SLT).

- While others reported that the study had a positive impact on the TAU services received by families:

  “being aware that someone from Michael Palin Centre is going to be taking a look at what you’re doing in your therapy sessions, I think, that is a factor that might change what Treatment As Usual actually looks like" (06 SLT)

  "on the REDCap checklist, it asks about homework given for parents, homework given for the child, that, also, just things like that, make me go oh, yes, did I specifically give the child versus the parents’ homework" (05 SLT)

- The experience of completing the assessment battery was mixed, for some it was perceived as lengthy and burdensome, while for others it was easy or helpful:

  "just repetitive. It just kept saying the same thing. It was just a bit annoying" (22 child).

  "he wasn’t really that motivated to fill them in. I think he found them quite long" (13 parent).

  "They’re really easy to complete" (10 child).

  "What was really nice about those questionnaires that we did is actually spending that time with him, going through them, and actually looking at how we did feel" (15 parent).

  In any future trial it will be necessary to reduce the burden of data completion on child participants, not only to maximise participation and engagement at follow up (as reported in Section 3.2), but also to increase their satisfaction with the research experience.

- The participants emphasised the importance of having strong support from the research team:

  "I felt very informed. Very informed and very included" (25 parent).

  "I was happy that there was that support there with just trying to coordinate families” (07 SLT).

- The opportunity for the research team to meet the child participants and engaging with them to record the speech samples, was an opportunity for them to ask questions, complete questionnaires with support, and for the research team to encourage engagement with the data collection processes.

3.4. Objective 4: delivery and fidelity of palin STSC(8−14)

Treatment fidelity has rarely been evaluated in the field of stuttering (Hofslundsengen et al., 2022). In this study, the treatment fidelity analysis showed that overall adherence to the Palin STSC(8−14) programme by SLTs was 85.7 %. The session in which SLTs provided feedback to parents regarding the assessment results and the rationale for therapy yielded the lowest fidelity score (71.3 %). Fidelity to treatment in the 10 therapy sessions ranged from 78.3 % to 94.3 % The high levels of adherence by the SLTs in the trial is pleasing and support the training methods. These results demonstrate that SLTs are able to implement this therapy in local contexts and with limited experience. The method of developing the fidelity measure ensured that content validity was high. Inter-rater reliability between the two researchers rating treatment fidelity was ‘almost perfect’ (McHugh, 2012) (k = 0.813; 95 % CI [0.782, 0.843]).

3.5. *Objective 5: health economics*

The completion rate for each resource-use item in the (proxy) CA-SUS was between 21 and 24/24 (11 and 12/24) for TAU at baseline (6 month follow up), compared to between 27 and 32/32 (17 and 19/32) for Palin STSC(8−14) (6 month follow up) (see Table 6). There was negligible additional educational support, other health care contacts, equipment/other costs or extra care accessed by either treatment arm either before or at the end of therapy. The results suggest that the greatest resource accessed by children who stutter is Speech and Language Therapy, including those children where anxiety levels reached clinical thresholds.

The CHU-9D was completed by all the participants (n = 24 TAU and n = 32 Palin STSC(8−14)) at baseline, compared to 11 and 16, respectively, at 6 months follow up (see Table 4). Mean CHU-9D scores improved in both arms for those who completed the measure at both baseline and 6 month follow up.

Table 6
Levels of education and resource use at baseline and follow up.

	Baseline		*6 month follow up*	
Resource use, mean value (standard deviation) n	*Treatment As Usual (N = 24)*	*Palin STSC (N = 32)*	*Treatment As Usual (N = 24)*	*Palin STSC (N = 32)*
1:1 SLT Palin Stammering Therapy (n sessions)	-	-	-	6.88 n = 32
Total session time, minutes	-	-	-	449 n = 30
1:1 SLT TAU (n sessions)	-	-	3.46 n = 24	-
Total session time, minutes	-	-	229 n = 24	-
Education setting: Mainstream school: Yes (%)	21 (100 %) n = 21 *	26 (96.3 %) n = 27 *	11 (100 %) n = 11 *	17 (100 %) n = 17 *
Any health contacts / educational support†: Yes / No	6 / 18 n = 24	3 / 29 n = 32	6 / 6 n = 12	4 / 15 n = 19
1:1 SLT (at school) ‡ [No./n]	0 (0) [0/24]	0 (0) [0/32]	0 (0) [0/12]	0 (0) [0/19]
Shared SLT (i.e. in a group) (at school) ‡ [No. / n]	0 (0) [0/24]	0.12 (0.68) [1/32]	0.03 (0.10) [1/12]	0 (0) [0/19]
1:1 learning support assistant (at school) ‡ [No. / n]	0.77 (3.77) [1/24]	0 (0) [0/32]	0.10 (0.54) [1/12]	0 (0) [0/19]
Shared learning support assistant (at school) ‡ [No. / n]	0.64 (3.14) [1/24]	0.02 (0.10) [1/32]	0 (0) [0/12]	0.08 (0.35) [1/19]
Other (at school) ‡ [No. / n]	0.01 (0.03) [3/24]	0 (0) [0/32]	0 (0) [0/11]	0.00 (0.01) [1/19]
1:1 SLT Palin Stammering Therapy × [No. / n]	0 (0) [0/24]	0 (0) [0/32]	0.67 (2.31) [1/12]	1.16 (2.87) [3/19]
1:1 SLT × [No. / n]	0 (0) [0/24]	0.09 (0.53) [1/32]	1.92 (3.03) [4/12]	0 (0) [0/19]
Shared SLT (i.e. in a group) × [No. / n]	0 (0) [0/24]	0 (0) [0/32]	0 (0) [0/12]	0 (0) [0/19]
Community based counsellor × [No. / n]	0 (0) [0/24]	0.19 (1.06) [1/32]	0 (0) [0/12]	0 (0) [0/19]
Clinical psychologist × [No. / n]	0 (0) [0/24]	0 (0) [0/32]	0 (0) [0/12]	0 (0) [0/19]
Child and adolescent psychiatrist × [No. / n]	0 (0) [0/24]	0 (0) [0/32]	0 (0) [0/12]	0 (0) [0/19]
Other CAMHS* professional × [No. / n]	0.13 (0.61) [1/24]	0 (0) [0/32]	0 (0) [0/12]	0 (0) [0/19]
Hospital Doctor × [No. / n]	0.25 (0.90) [2/24]	0.19 (0.90) [2/32]	0 (0) [0/12]	0.11 (0.46) [1/19]
Nurse × [No. / n]	0.08 (0.28) [2/24]	0 (0) [0/32]	0.08 (0.29) [1/12]	0.11 (0.46) [1/19]
General Practitioner (GP) × [No. / n]	0 (0) [0/24]	0.03 (0.18) [1/32]	0.17 (0.58) [1/12]	0.05 (0.23) [1/19]
Occupational therapist × [No. / n]	0.04 (0.20) [1/24]	0 (0) [0/32]	0 (0) [0/12]	0 (0) [0/19]
Social worker × [No. / n]	0 (0) [0/24]	0 (0) [0/32]	0 (0) [0/12]	0 (0) [0/19]
Community care assistant × [No. / n]	0 (0) [0/24]	0 (0) [0/32]	0 (0) [0/12]	0 (0) [0/19]
Advice from charity × [No. / n]	0 (0) [0/24]	0 (0) [0/32]	0 (0) [0/12]	0.05 (0.23) [1/19]
Other × [No. / n]	0 (0) [0/24]	0 (0) [0/32]	0 (0) [0/12]	0 (0) [0/19]
Any specialist equipment / other extraordinary costs (as a result of your child’s stammer)?: Yes / No	0 / 24 n = 24	0 / 32 n = 32	0 / 11 n = 11	0 / 19 n = 19
Any extra care (as a result of your child’s stammer)?: Yes/No	0 / 24 n = 24	0 / 32 n = 32	1 / 10 n = 11	1 / 18 n = 19

n - number of participants for whom data were available; * At baseline (6 months) 1 (1) TAU participant and 2 (1) Palin STSC reported that they had a home tutor, as well as attending a mainstream school; †any hospital appointments, additional education support, or any community based professional contacts / services; ‡ Hours per week across the 6 month period; No.=number of patients in receipt of the resource item in question i.e. excluding zero values; ×Total number of contacts that took place, in each type of setting, in the last 6 months; SLT = Speech and language therapist

A total of 83 sessions were recorded to have taken place across the treatment as usual children who stutter (n = 24), compared to a total of 220 sessions across the 32 Palin STSC(8−14) children who stutter. Actual times were recorded for 298 of these sessions (98 %). Based on the active therapists and child-parent dyads (i.e. those attending at least one session), children in the Palin STSC(8−14) therapy received more sessions of therapy (M = 8.1, SD = 3.35) than those in TAU (M = 3.8, SD = 2.27).

Costs were calculated according to NHS pay levels that were relevant at the time for the staff involved in the study. When the trainer was costed at an NHS clinical employment band 8b (£88.43 per hour) (Jones & Burns, 2021) for 14 hours of preparation and 10 question and answer sessions (30 minutes each), and an SLT at the mean of Band 6 and Band 7 (£59 per hour) (Jones & Burns, 2021) for the 20 hour training programme and one question and answer session (undertaken by 19 SLTs), training costs were estimated to be £ 774.97 per child when equally apportioned across the 32 Palin STSC(8−14) children. Each SLT was also provided with video recording equipment at a cost of £ 77.88 per SLT (equivalent to £46.24 per child across the 32 Palin STSC(8−14) children). In terms of the Palin STSC(8−14) intervention each of the 32 children received an assessment (an estimated 3.25 hours of SLT time) (cost=£192.90 per child) and the mean number of Palin STSC(8−14) therapy sessions was 6.88 per child for an average time of 68 minutes (this includes an assumed 15 minutes per session for preparation before and note writing afterwards) (cost=£466.59 per child). This equates to a total Palin STSC cost of £ 1480.71 per child for the training, equipment, assessment and therapy session costs. Across the 24 TAU children, the mean number of therapy sessions was 3.46 for an average time of 66 minutes (again including 15 minutes for preparation/note writing) (total cost=£228.96 per child). The mean incremental cost of the Palin STSC(8−14) intervention, compared to TAU, was thereby estimated to be £ 1251.75 per child (or £476.78 per child when SLT training costs were excluded).

3.6. Estimating the sample size of a future trial

Based on feedback from the Project Advisory Group, the priorities for therapy identified by the SLTs during the semi-structured interviews, and the areas of change highlighted by parents post therapy, impact of stuttering was selected as the primary outcome for a future trial. The sample size is based on the OASES Total Impact score obtained in the feasibility study. As there were insufficient follow-up data to get an estimate of the intraclass correlation coefficient, the baseline data has been used instead. These provide 90 % power for an effect size of 0.4 (which is easily consistent with the pilot data). To allow for 10 % drop out rate, we will seek to recruit 124 SLTs (62 per arm) and 372 child participants (186 per arm).

4. Study summary and limitations

The aim of this study was to examine the feasibility of a definitive randomised controlled trial to compare the effectiveness and cost effectiveness of Palin STSC(8−14) with usual therapy in the NHS. There were five objectives: 1) to establish recruitment and participation rates; 2) to examine the suitability of the outcome measures; 3) to explore the acceptability of the intervention and research methods; 4) to determine treatment fidelity for Palin STSC(8−14); and 5) to assess the appropriateness of cost-effectiveness measures. Recruitment targets were exceeded (37 SLTs and 67 children with parents) and results showed that the research and therapy methods were largely acceptable. The changes made in response to the pandemic proved beneficial, but there is a need to reduce the assessment burden for the children in any future trial. The retention of SLTs and the results of the fidelity evaluation support the training methods and show that SLTs can implement this therapy in local contexts. Overall, the findings support a fully powered RCT, but there were limitations in this study which should be considered in future.

The aim of this therapy is to provide SLTs who are not specialists in stuttering, with a first line therapy programme that they can use without the need for specialist input, thereby increasing access to services and protecting specialist services for those who need them most. Almost half of the SLTs in this trial were specialists, with additional stuttering knowledge and experience. This may have influenced their ability to implement the therapy with such high levels of fidelity. In a future trial, recruitment of non-specialist SLTs will be prioritised.

Due to the timescale and the resources of the study, there were limitations to the ability to keep the research assistants blind for the purposes of the speech sample analysis and the interviewing. While checks were incorporated to ensure the reliability of the data, a future trial should include additional processes to increase blindness to time and person when analysing speech samples.

Despite the population in this study having been recruited from a range of advantaged/disadvantaged backgrounds, it was predominantly white British and not necessarily reflective of the ethnic diversity of the recrutiment sites. For a definitive trial, a representative, ethnically diverse population needs to be established. It was not possible to provide translated materials or interpreters within this trial, but providing these in a future study will be prioritised and will hopefully facilitate engagement.

This study was designed with the follow up data collection taking place six months after the baseline data collection. It was anticipated that the clinical assessment would take place close to the baseline, with the ten Palin STSC(8−14) therapy sessions completed within 14 weeks after that. However, delays resulting from holidays, sickness, COVID-19 isolation restrictions and service limitations meant that the process was often longer, with little time for generalisation and consolidation of new knowledge and skills before the follow-up assessment. For a small number of children, therapy was not completed ahead of the follow-up assessment. The follow up period was limited in this study due to resources, but a future study will need a longer follow up period to explore the impact of the therapy on day-to-day functioning, participation and well-being over the medium term.

5. Conclusions

The objectives of this feasibility study were met. Recruitment and attrition figures, adherence to the research procedures, high treatment fidelity, positive experiences of the therapy and research, as well as early indications of effectiveness, all support the need and viability for a definitive trial to investigate the effectiveness and cost-effectiveness of Palin STSC(8−14) compared to Treatment as Usual in the NHS.

Ethical approval

Ethical approval was obtained on 17th June 2019 (Bloomsbury Research Ethics Committee, REC reference: 19/LO/0933; IRAS number: 251914).

Declaration of Competing Interest

The author, Sharon Millard, is an Editorial Board Member for Journal of Fluency Disorders and was not involved in the editorial review or the decision to publish this article. The authors declare the following financial interests/personal relationships which may be considered as potential competing interests. Dr Sharon Millard is employed at the Michael Palin Centre for Stammering, where this therapy was developed.

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Data availability

Data will be made available on reasonable request.

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