The SUPPORT Study: Supporting Caregivers with a mobile app for children who stammer aged 8–12 years

Supporting Caregivers with a mobile app for children who stammer aged 8–12 years: A mixed method, randomised controlled, open label, multi-centre study to investigate the feasibility and acceptance of the Super Penguin mobile application plus usual care compared to usual care alone in families of children aged 8-12 years old who stammer.

Version and Date of Study Protocol:	V4.0 19Jun2026
Sponsor:	BeneTalk Ltd
Chief Investigator:	Dr Patricia Holch
IRAS Number:	333572
ISRCTN	60636241
Funder(s):	National Institute of Health and Social Care Research (NIHR) NIHR206439
This protocol has regard for the HRA guidance	

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host NHS Trust, regulatory authorities, and members of the Research Ethics Committee.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, Medical Devices Regulations 2002, ISO 14155:2020, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the study without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies from the trial as planned in this protocol will be explained.

Protocol version 4.0 19/Jun/2026 authorisation signatures:

Chief Investigator:		
Signature:		Date:
	……..	
Name (please print):	DR PATRICIA HOLCH READER IN APPLIED HEALTH PSYCHOLOGY	
	……..	

For and on behalf of the Trial Sponsor (if required):		
Signature:		Date:
Name (please print):	DR RONAN MILLER ……..	
Position:	DIRECTOR OF REAL-WORLD EVIDENCE (Co-Investigator)	
	……..	

KEY TRIAL CONTACTS

Chief Investigator:	Dr Patricia (Trish) Holch Reader in Applied Health Psychology Director PsyCen (Centre for Psychological Research) Psychology, Humanities and Social Sciences Leeds Beckett University, Portland Building, City Campus Leeds LS1 3HE t.holch@leedsbeckett.ac.uk
Co-Investigator(s):	Dr Ronan Miller BeneTalk Ltd Flat 7 Foxgrove House, Foxgrove Road, Beckenham, Kent, England, BR3 5AR Ronan@superpenguin.com Other co-applicants: Jordi Fernandez BeneTalk Ltd Flat 7 Foxgrove House, Foxgrove Road, Beckenham, Kent, England, BR3 5AR jordi@superpenguin.com Dr Apostolos Fakis Derby Clinical Trials Support Unit Royal Derby Hospital Uttoxeter Road Derby, DE22 3NE apostolos.fakis@nhs.net Nicola Maddy Children's speech and language therapy department The Lodge Kendray Hospital Doncaster Road Kendray Barnsley S70 3RD nicola.maddy@swyt.nhs.uk Ben Bolton- Grant Leeds Beckett University City Campus Leeds

	United Kingdom LS1 3HE b.bolton-grant@leedsbeckett.ac.uk Catherine Woolley STAMMA Box 140 43 Bedford Street London WC2E 9HA Catherine.Woolley@stamma.org Heather Bridgen-McLean (PPI Rep) Heatherbrigdenmclean@hotmail.com
Trial Manager/ Co-ordinator:	Andrew Skeggs Clinical Trial Manager Derby Clinical Trials Support Unit Uhdb.superpenguin@nhs.net
Sponsor:	BeneTalk Ltd Flat 7 Foxgrove House, Foxgrove Road, Beckenham, Kent, England, BR3 5AR speak@superpenguin.com
Funder(s):	National Institute of Health Research (NIHR) via THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE 39 Victoria Street, Westminster, London, SW1H 0EU alex.zabalafindlay@nihr.ac.uk
Clinical Trials Unit:	Derby Clinical Trials Support Unit Royal Derby Hospital Uttoxeter Road Derby, DE22 3NE 01332 724639 uhdb.superpenguin@nhs.net
Trial Statistician:	Komel Khabra Medical Statistician Derby Clinical Trials Support Unit Uhdb.superpenguin@nhs.net
Data Manager	Zak Connan Clinical Trials Data Manager Derby Clinical Trials Support Unit uhdb.superpenguin@nhs.net

TRIAL SUMMARY

Trial Title:	**The SUPPORT Study:** Supporting Caregivers with a mobile app for children who stammer aged 8–12 years: A mixed method, randomised controlled, open label, multi-centre study to investigate the feasibility and acceptance of the Super Penguin mobile application plus usual care compared to usual care alone in families of children aged 8-12 years old who stammer.	
Protocol Reference:	UHDB/2023/027	
Trial Design:	A mixed-methods, multi-centre, prospective, 2-arm, randomised controlled, open label, feasibility study	
Trial Participants:	Caregivers of children who stammer (CWS) aged 8-12 years old	
Planner Number of Sites:	3-4	
Planned Sample Size:	N=34 participants (caregivers of children aged 8-12).	
Duration of participation:	Participants will be on the study for a maximum of 11 months from consent and randomisation.	
Planned Start Date:	01 December 2025	
Planned Recruitment End Date:	31 August 2026	
Planned Study End Date:	31 October 2027	
	Objectives	**Outcome Measures**
Primary:	To evaluate the feasibility of the SuperPenguin app as an adjunct to standard NHS speech and language therapy for caregivers of children who stammer (CWS).	• Eligibility, approached, consent and randomisation rate • Completion of outcomes • Completion of participation • Usage data • Treatment allocation adherence Reasons for non-randomisation and drop outs
Secondary:	1. To evaluate user safety, usability engagement and acceptability with the app. 2. To assess satisfaction and perceived impact on therapy outcomes. 3. To analyse potential cost savings for the NHS.	1. Participant and therapist reported outcome measures (PPRS, SFBT, TOMs, MAUQ) 2. Semi-structured interviews exploring barriers and facilitators to use 3. Economic Viability (EQ5D-3L and Resource Use Questionnaire). 4. Safety
Medical Device:	SuperPenguin mobile application	
Eligibility Criteria:	Caregivers of children who stammer aged 8-12 years old accessing NHS speech and language therapy.	

FUNDING AND SUPPORT IN KIND

Funder(s)	Financial and Non-Financial Support Given
The Secretary of State for Health and Social Care via the National Institute for Health and Care Research 39 Victoria Street, Westminster London, SW1H 0EU alex.zabalafindlay@nihr.ac.uk	This trial is funded by the NIHR i4i Product Development Award **NIHR206439**.
British Stammering Association (STAMMA)	Catherine Woolley - PPI co-applicant
Action for Stammering Children (ACS)	Providing support related to PPI, dissemination of recruitment materials and project outcomes

ROLES & RESPONSIBILITIES

Sponsor

BeneTalk Ltd. is the legal Sponsor of this feasibility study. The study is funded by the NIHR (i4i Product Development Award NIHR206439). BeneTalk ensures appropriate research funding and governance are in place.

Funder

The study is funded by National Institute of Health Research (NIHR) via The Secretary of State for Health and Social Care

Study Management Committees

Trial Management Group

The Trial Management Group (TMG) will meet regularly to oversee the day-to-day management of the trial, including all aspects of the conduct of the trial. Any problems with study conduct and participating centres will be raised and addressed during TMG meetings.

Trial Steering Committee

A Trial Steering Committee (TSC) will be convened to meet at least annually to oversee and supervise the progress of the trial and ensure that it is being conducted according to the protocol and the applicable regulations. The TSC is an independent body that includes majority members who are not involved with the running of the trial.

Protocol Contributors

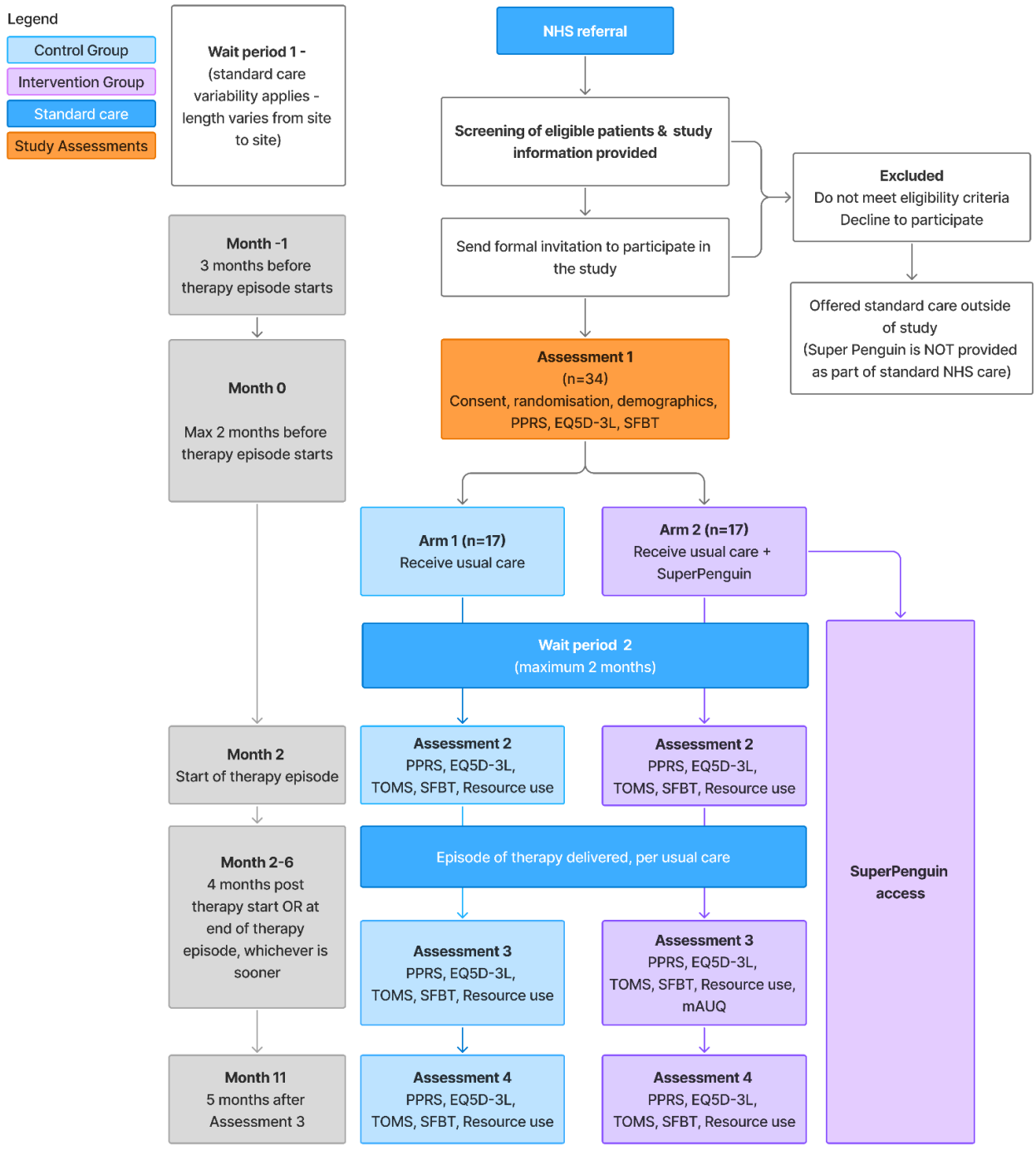
Several contributors have been involved in the development of the protocol, these include; the Chief Investigator, Statistician, Data Manager, Trial Manager, Sponsor, PPI reps and co-applicants. Contributors are responsible for inputting into the design of the study, ensuring that it is designed transparently and efficiently.

Contents

LIST OF ABBREVIATIONS

AE	Adverse Event
CI	Chief Investigator
CRF	Case Report Form
CWS	Children who stammer
DMEC	Data Monitoring and Ethics Committee
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
IB	Investigator Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use.
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trials
NHS	National Health Service
NHS R&D	National Health Service Research & Development
PCI	Parent-child interaction (therapy)
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
PWS	People who stammer
QA	Quality Assurance
QC	Quality Control
QoL	Quality of Life
RCT	Randomised Control Trial
REC	Research Ethics Committee
RTA	Reflexive Thematic Analysis
SAE	Serious Adverse Event
SDV	Source Data Verification
SLT	Speech and language therapist
SOP	Standard Operating Procedure
SPMA	SuperPenguin Mobile App
TDF	Theoretical Domains Framework
TMG	Trial Management Group
TSC	Trial Steering Committee
TMF	Trial Master File

STUDY FLOW CHART



1. BACKGROUND

Stammering (also known as stuttering) is a form of speech, language and communication difference that occurs in an estimated 5-8% of children and approximately 1% of the general population [1]. Typically stammering begins when children are aged 2-5 years but can also begin in older childhood or adulthood [2]. Children who stammer (CWS) are generally observed to have interrupted speech production or fluency, characterised by repetition or prolongation of sounds and words, hesitations, and periods when speech appears blocked [1, 3, 4]. Often compared to an iceberg, it is important to recognise that it is the *less* visible aspects of stammering that can have a greater impact on day-to-day life [5-8]. Physical aspects, such as repetition and prolongation, are observable by others, while psychological and emotional aspects including feelings of embarrassment and frustration sit 'below the water's surface' [5, 6, 8]. Wider systemic issues, such as childhood bullying, social stigma, and stereotypes of people who stammer (PWS) all sit 'around' the iceberg and can negatively impact on a PWS's experience of talking and their social and emotional wellbeing [6, 8, 9].

Reports from parents/carers of CWS suggest that stammering can affect a child's mood, wellbeing, and self-esteem, and for some children can cause withdrawal in social situations [10]. Stammering continues into adulthood for some children [2] which has been found to be associated with anxiety and social phobia [9, 11, 12] and reduced social, educational, and occupational quality of life [13]. Early intervention for CWS is therefore critical [4, 9, 14], particularly as it can be challenging to provide effective support in adolescence and adulthood [4]. Professional services to support children's satisfaction and confidence with communication whether or not it includes stammering should be available for *all* CWS who would like it [3]in a way that is tailored to the individual needs of each child [15, 16].

Traditionally, support for CWS has focussed on providing a direct intervention to promote speech fluency by praising stammer-free speech and gently correcting stammering [12-14]. While these direct approaches, such as the Lidcombe Program e.g., [17, 18], have been found to be effective at reducing stammering for pre-school aged children (i.e., <7 years) [13, 19], they are now increasingly under criticism [20, 21]. In-line with the social model that emerged from the disability rights movement, there has been a shift away from pathologizing stammering and viewing it as a deficit that needs fixing (i.e., by promoting speech fluency) towards viewing it as a difference that instead requires acceptance from the wider society and support for PWS to develop positive stammering identities [8, 20, 21]. Accordingly, alternative approaches to support CWS aim to enable children to accept their stammer, decrease behaviours such as avoidance and effort to control stammering, and ultimately have the confidence to communicate happily and freely [20, 21]. Further, support can focus on modifying the child's surroundings, such as parents/carers adjusting their own verbal interactions, to create a supportive environment for the child [12-14].

Notably, stammering can affect children's caregivers, as well as the children themselves [12, 15, 22]. For example, caregivers have reported feeling unsure what to do when their child stammers, can have concerns that their child's stammer has affected communication between them, may feel uncertainty about whether stammering should be acknowledged in the home environment, and can worry about the possible impact of stammering on their child's life including ability to make friends, negative emotions, and social rejection [12, 15, 23]. Support for CWS should therefore also consider the needs

and concerns of caregivers; caregivers need to be supported to recognise and develop their skills and confidence in supporting their child [12, 23], and in feeling confident in their child's communication regardless of whether or not their child stammers.

'SuperPenguin' is a novel mobile application that has been designed with input from caregivers of CWS and speech and language therapists (SLTs) to work alongside National Health Service (NHS) speech and language therapy. The app aims to educate caregivers about stammering and help them in creating a facilitative and supportive communication environment for their child. The app features exercises and resources to support core speech and language therapy activities that can be personalised to the individual family. SLTs (n = 62) have provided clinical input into the content and design of SuperPenguin for parents of CWS. Caregivers of CWS (n = 25) have been involved in interviews to determine user needs, develop the app specifications, and provide iterative feedback throughout the development of SuperPenguin. For example, caregivers highlighted that anxiety around school, particularly starting at a new school, was common. This led to the incorporation of app modules to guide families in how to approach school and talk to teachers. Overall, SuperPenguin is designed to empower caregivers by increasing their confidence in supporting a child's communication development while reducing anxiety and stress. In turn, this fosters a more supportive communication environment for CWS.

2. RATIONALE

Despite the importance of early intervention for CWS and their caregivers, NHS support for stammering is currently not accessible to all children who need it. Despite the recognised importance of early intervention for children who stammer (CWS) and their caregivers, NHS provision remains uneven. A 2024 Freedom-of-Information survey of 125 NHS Trusts in England found that only 65 of 118 respondents (55 %) offered any paediatric speech-and-language-therapy (SLT) service for stammering, leaving 45 % of Trusts with no provision at all. Among the Trusts that do provide a service, 92 % reported a dedicated dysfluency pathway and/or a specialist SLT, yet five Trusts lacked both [24].

Further, there is no standardised pathway of care within the NHS for CWS with a wide variety of approaches to implementing support existing [25]. This uneven access to support results in a 'postcode lottery' with the support available to children being determined by where they live [3, 25].

The SuperPenguin app offers a potential solution to ensure *all* families can access speech and language support, regardless of where they live. SLTs will be able to recommend the app to caregivers while they wait for NHS services, helping to provide the necessary early intervention for CWS and potentially increasing SLT capacity and, in turn, reducing wait times. SuperPenguin can continue to be used alongside receipt of speech and language services, as well as after services have been completed, helping to provide the tailored support that CWS and their families need.

While some mobile applications are available for PWS, none have gained widespread clinical adoption because of insufficient scientific evidence. Further, the existing apps focus primarily on speech output. As described above ("Background"), support for CWS that is speech-focussed is increasingly criticised. There is thus a need for a digital solution that helps families to create a facilitative, supportive

communication environment for their child and helps them build successful positive interactions with their children.

To ensure the effectiveness of SuperPenguin is rigorously tested such that it can be integrated into routine NHS care, a randomised controlled trial (RCT) is necessary. Importantly, it has been noted that sufficient RCT evidence is currently lacking within available stammering therapy [19]. The aim of the current study is therefore to test the clinical feasibility of the SuperPenguin app to develop a future definite RCT in which the clinical and cost effectiveness of SuperPenguin within NHS speech and language therapy pathways will be tested.

2.1 Control Interventions and Comparators

The control group in this study will receive standard NHS speech and language therapy, while the intervention group will receive access to the SuperPenguin app in addition to standard NHS speech and language therapy. This design ensures that no participants are denied or delayed standard care.

The choice of standard therapy as the control is justified because it reflects the current NHS best practice for treating children who stammer. By comparing the outcomes of standard therapy alone with those of therapy plus the digital therapeutic, we will determine whether SuperPenguin provides added value in terms of therapy outcomes, therapy engagement and quality of life (QoL).

2.2 Assessment and Management of Risk

Table 1 Risk Assessment

Category	Details
Known and Potential Risks	Minimal risks, primarily user frustration with technology or lack of engagement. No severe adverse device effects expected.
Anticipated Clinical Benefits	- Enhances therapy adherence and outcomes for children who stammer (CWS). - Reduces anxiety and boosts caregiver confidence. - Improves CWS quality of life.
Risks Associated with Participation	Minimal risks, such as potential frustration with the app or usability challenges. Addressed through regular monitoring and support. Qualitative interviews: potential for some participants to feel upset by having a discussion about stammering and speech and language therapy.
Possible Interactions with Concomitant Medical Treatments	No anticipated negative interactions with existing NHS speech and language therapy practices or other medical treatments.
Risk Level Compared to Standard Practice	Low risk compared to standard NHS speech and language therapy. Minimal additional risks introduced using SuperPenguin.
Risk Control, Minimisation, and Management	- Adequate participant support provided for app usage. - Regular check-ins to monitor engagement. - Ethical and data protection safeguards in place. Qualitative interviews: clear distress protocols have been put in place for interviewers to follow should a participant of any age become upset by

	the topic of conversation in the interview. Information sheets will direct participants to further support if needed. For children's interviews, children will be given the option of having their caregiver present. Where caregivers are not present, the interviewer will have caregiver contact details and caregivers will be asked to be nearby should the interviewer need to contact them at any point in the child's interview.
Rationale for Benefit-Risk Ratio	The potential benefits, including improved therapy outcomes, reduced waiting times, and enhanced well-being, far outweigh the minimal risks associated.

3. OBJECTIVES AND OUTCOME MEASURES/ ENDPOINTS

Primary Objective:

To assess the feasibility of the SuperPenguin app as an adjunct to standard NHS speech and language therapy for caregivers of children who stammer (CWS).

Research Question (PICOT):

- **P**: Caregivers of CWS aged 8 to 12 years.
- **I**: SuperPenguin app in addition to NHS speech and language therapy.
- **C**: Standard NHS speech and language therapy alone.
- **O**: Feasibility (recruitment/retention), adherence, signal of efficacy.
- **T**: Follow-up assessments at baseline, start/end of therapy and 5 months post-therapy.

Secondary Objectives:

- Usability, Safety and Acceptability: To assess the safety, usability and acceptability of the SuperPenguin app among caregivers and SLTs.
- Caregiver Engagement: To evaluate caregiver engagement with the app.
- Caregiver confidence and anxiety reduction.
- Intervention fidelity: to assess whether the intervention has been delivered to caregivers the way it was anticipated.
- Economic viability: To make a preliminary assessment of the economic viability of SuperPenguin implementation into NHS pathways.

Primary Endpoint / Outcome:

The primary endpoint of this study will be the feasibility of the SuperPenguin app in NHS care pathways, measured by:

- Eligibility, approached, consent and randomisation rate
- Completion of participant- and therapist- reported outcomes; PPRS, TOMs, SFBT, and MAUQ
- SuperPenguin Usage Data, collected by the app and will include the following:

Individual data:

- Total usage time (minutes)
- Number of sessions (app launches)
- Usage period (date of first and last recorded session)

  - Topics completed (count and topic names)
  - Responses to CarerQoL assessment (progress values)
  - Responses to SFBT assessment (progress values)

Aggregated data:
  - Topic completion distribution
  - Number of downloads/registrations by site / region
  - Percentage of referral-to download (percentage of referral / account creation vs first-login conversion)
  - App usage/retention metrics at 7 and 30 days (Cohort-level engagement curves)
  - Responses to CarerQoL assessment (progress values)
  - Responses to SFBT assessment (progress values)

- Completion of participation at 5 months post therapy
- Treatment allocation adherence
- Reasons for non-randomisation and withdrawal

Secondary Endpoints/ Outcomes:
- Caregiver confidence: Assessed using the Palin Parent Rating Scales (PPRS) to measure the parents' ability to support their child's therapy. This will be assessed at 0-2 months pre-therapy, at the start of therapy, max 4 months after start of therapy and 5 months after previous assessment.
- Caregiver "Best Hopes": Measured using the Solution-Focused Brief Therapy measures (SFBT). Assessments will take place at timepoints: 0-2 months pre-therapy, at the start of therapy, up to 4 months after the start of therapy, and 5 months after the previous assessment. For participants in the intervention arm, SFBT measures will also be collected frequently via the app as part of the intervention. However, only the data collected at the four specified timepoints will be used for outcome analysis in the study.
- Therapy Outcome Measures (TOMs) assessed at the start of therapy, max 4 months after start of therapy and 5 months after previous assessment. The "Dysfluency" TOM scale will be used (herein referred to as "TOMs")
- Caregivers' and SLTs' perceptions of app usability, and acceptability: Collected using semi-structured interviews. A subset of caregivers (n=5-10) and SLTs (n=5-10) will participate in interviews
- Caregiver Engagement: To evaluate caregiver engagement with the app, measured by frequency of use, completion of activities, and feedback collected via semi-structured interviews.
- Usability: Assessed using mHealth App Usability Questionnaire (MAUQ) for the intervention group only. This will be assessed at the end of therapy.
- Safety: the safety of the intervention will be assessed via device deficiencies, Adverse Device Effects, Serious Adverse Device Effects, and Unanticipated Serious Adverse Device Effects. In addition, general Adverse Events (AEs) and Serious Adverse Events (SAEs) will be collected for participants in both arms.
- Economic viability: Assessed using the Resource Use questionnaire and EQ5D-3L to explore the financial impact of integrating SuperPenguin into NHS speech and language therapy.

- Children's confidence and happiness communicating: Evaluated through semi-structured interviews with children (8-12 years) who stammer (n = 5-10).
- Caregivers' and SLTs' perceptions of trial design acceptability: Evaluated through semi-structured interviews with caregivers (n = 5-10) and SLTs (n = 5-10).

4. TRIAL DESIGN

The trial is designed as a multi-centre, two-arm, open label, randomised controlled feasibility study with a mixed-methods approach, focusing on caregivers of children who stammer (CWS). The purpose of this design is to inform the development of a definitive randomised controlled trial (RCT) evaluating the clinical and cost-effectiveness of SuperPenguin.

- Study Arms:
    - Usual NHS speech and language therapy (control arm). Caregivers will access NHS speech and language therapy, in line with the usual care for the participating organisation. Access to SuperPenguin Mobile App (SPMA) will not be provided.
    - Intervention arm: In addition to accessing NHS speech and language therapy, caregivers will have access to SPMA, which provides additional therapeutic support, resources, and activities designed to complement traditional therapy.

4.1 Progression Criteria

The stop-go criteria for progression to a definitive RCT are as follows:

1) <u>Total Recruitment (of expected sample size)</u>

- Green (go): ≥ 80% of the intended sample size is randomised, i.e. at least 27 participants.
- Amber (consider proceeding): Randomisations falls between 40% and 80%, i.e. 14 to 26 participants inclusive.
- Red (stop): Randomisations falls below 40%, i.e. 13 or less participants.

2) <u>PPRS completion rate</u>

- Green: ≥80% (Consider suitable as primary endpoint of definitive-RCT)
- Amber: 80%-40% (Consider suitable as primary endpoint of definitive-RCT with necessary adjustments)
- Red: <40% (Do not consider suitable as primary endpoint of definitive-RCT)

3) <u>Adherence</u>

- Green: >=90% of study participants download the app and complete at least one topic. Proceed to main trial.
- Amber: 40%-90% of study participants download the app and complete at least one topic. Proceed to main trial with modifications.
- Red: <40% of study participants download the app and complete at least one topic. Do NOT proceed to main trial.

Industry data confirm that sustained engagement and adherence with mobile digital-health apps is rare: in a systematic usage analysis of 93 popular mental-health apps, median 15-day retention was 3.9 % and median 30-day retention just 3.3 % [26]. Compared with these real-world baselines, setting a feasibility target in which ≥ 40 % of SuperPenguin participants download the app and complete at least one therapeutic topic is both pragmatic and ambitious, demanding performance roughly an order of magnitude above typical unguided use.

Evidence from an NHS stepped-care trial of the established SilverCloud platform shows that about three-quarters of users (≈ 75–89 %) complete at least one lesson and roughly half progress through the full programme [27]. Placing the amber zone adherence rate for this study between 40 % and 90 % therefore brackets its expected performance between a realistic threshold for a novel app and the upper range achieved by a mature comparator, while mirroring the red/amber/green progression framework recommended for pilot studies [28].

In addition, qualitative interviews will be conducted to gather in-depth feedback from caregivers, speech and language therapists (SLTs), and children (aged 8-12 years) who stammer. Interview aims are as follows:

1. To investigate the acceptability, and usability of the SuperPenguin app from the perspectives of caregivers (n = 5-10) and SLTs (n = 5-10).
2. To investigate the acceptability of the feasibility study design from the perspectives of caregivers (n = 5-10) and SLTs (n = 5-10).
3. To explore the perceptions and views of children who stammer (aged 8-12 years) regarding talking and receiving help with talking (n = 5-10).

5. STUDY SETTING

This is a multicentre study taking place in NHS organisations providing speech and language therapy (SLT) services. Sites will identify families referred for assessment for stammering, recruit caregivers to the study, manage the delivery of the study protocol and speech and language therapy in line with their usual care. Speech and language therapists (SLTs) at each organisation will access a web-based dashboard for the SuperPenguin app to review their participants' engagement and usage data. More information is in Section 8.1.1.

Qualitative interviews:
All interviews will be conducted online using Microsoft Teams. For interviews conducted with children, caregivers will be asked to ensure that their child's interview takes place in a communal space in their home i.e., not in the child's bedroom. In instances where caregivers are not present for their child's interview, they will be asked to be at home and to provide their contact details for the interviewer to use should they be needed at any point in the interview.

6. ELIGIBILITY CRITERIA

Table 2 Eligibility Criteria

Main Feasibility Study		
Participant	**Inclusion**	**Exclusion**
Caregivers	• Aged 18 or over • Child has been referred for and has been assessed as requiring access to speech and language therapy in line with usual practice • Child is 8-12 years old	• Unable to provide informed consent • Unable or unwilling to complete study assessments in English. • Families with more than one child who stammers, 8-12 years old, and have both been referred for speech and language therapy
Additional criteria for qualitative interview study:		
Participant	**Inclusion**	**Exclusion**
Caregivers	• Participating in clinical feasibility study randomised to use SuperPenguin app • Can complete an online interview in English	• Unable to provide informed consent
SLTs	• Have assigned use of SuperPenguin to feasibility study participants • Can complete an online interview in English	• Unable to provide informed consent
Children who stammer	• Caregiver is participating in feasibility study and has been assigned SuperPenguin • Aged 8-12 years • Can take part in an adult-led speaking activity in English • Has been referred for speech and language therapy to support stammering	• Caregiver does not provide informed consent

7. TRIAL PROCEDURES

7.1 Participation Identification & Recruitment

Participants & Setting

Participants will be identified and recruited from NHS organisations providing NHS speech and language therapy (SLT) services who do not have access to the Penguin or SuperPenguin app.

The caregivers of children referred for SLT will be assessed against the eligibility criteria by members of the care team and given information about the study. They will be formally invited approximately 3 months before commencing their first therapy episode and approached to consent to take part a maximum of 2 months before commencing the therapy episode. Prior to this, usual care will proceed as normal, which will vary from site to site. If available at the participating site, a carer workshop will be offered to participants. Where more than one caregiver is present in a family, then the family will decide which caregiver will be the participant in the trial. Other family members may use SPMA as part of the "family & friends access" feature without being study participants as described in Section 8.1.2.

Where caregivers are not recruited, reasons will be recorded on the study database for reporting purposes, along with their self-reported age, gender, and ethnicity.

Study recruitment will continue until the target sample size of 34 caregivers is met.

Qualitative interviews:

Caregivers and Children -

Purposive sampling will be used when recruiting participants to qualitative interviews to ensure a broadly equal spread of caregivers and children spoken to: (1) at three different time points in the speech and language therapy journey (i.e., waiting for therapy, receiving therapy, after completing therapy); and (2) across the three collaborating NHS sites. The intention will be to interview one caregiver and one child at each time point, at each site (i.e., three caregivers from each site, three children from each site. Target sample sizes are therefore: caregivers n = 9; children n = 9. Follow-up interviews will be offered to *caregivers only* who participate while waiting for speech and language therapy.

SLTs -

Purposive sampling will be used to ensure a broadly equal spread of SLTs spoken to: (1) across the three different sites; and (2) at different stages of delivering speech and language therapy (i.e., SLTs who *have not* started delivering therapy to families participating in the study, and SLTs who *have* started delivering therapy to families participating in the study). The intention will be to interview one SLT at each stage of delivering therapy at each site i.e., two SLTs from each site. Target sample size for SLTs is therefore: n = 6. Follow-up interviews will be offered to any SLTs who participate when they have not started delivering therapy to families participating in the study.

7.2 Screening

Screening will begin when caregivers are referred for stammering, and they may be introduced to the study at this point. As commencement of therapy approaches, the SLT care team should review the eligibility criteria and formally invite caregivers to take part approximately 3 months before therapy commences.

Potential participants will be identified by the speech-language therapists (SLTs) or their team at each NHS site, who have access to patient records and can assess eligibility. Staff not part of the care team will not be involved in screening or recruitment pathways.

Caregivers who fail to meet eligibility criteria may be eligible for re-screening if parameters change. If this happens, they will be given a new study ID.

Qualitative interviews:
Only participants randomised to the Intervention group (i.e., using the SuperPenguin app) will be eligible for participation in the qualitative interviews given interviews primarily aim to evaluate the acceptability and usability of the app.

7.3 Consent

Site staff will provide the current approved Participant Information Sheet and study invitation letter to potential participants via email/SMS or together with the clinic appointment paper letter. After being provided with the study information, potential participants will be given an opportunity to discuss participation with the team, ask any questions they may have and go away to discuss with those external to the site/study team, if they wish. It must be clear to those approached to consent that participation in the study is voluntary and their access to care will not be affected if they decide not to participate. Caregivers who are interested in participating in the study will confirm agreement for the site staff to enter their email and/or mobile number in the study database to enable a link to the electronic consent form to be sent to them via email or-SMS. This initial consent to contact will be documented in the participant electronic health records.
. Consent will be self-completed online by the participant by entering their initials alongside each of the consent statements, their name and the date.

The Principal Investigator (PI) retains overall responsibility for the informed consent of participants at their site and must ensure that any person delegated responsibility to participate in the informed consent process is duly authorised, trained and competent according to the REC approved protocol, principles of Good Clinical Practice (GCP) and Declaration of Helsinki.

The consent process will ensure participants fully understand the trial's purpose, procedures, risks, and their rights. Consent must be completed during Assessment 1, which takes place 2 months prior to commencing therapy, before any study specific assessments are conducted. The main study

consent form will cover consent for participation in the main study. It will outline the study's objectives, procedures, risks, and benefits.

7.4 Qualitative Study Consent

Caregivers:

At the point of consent and randomisation to the feasibility trial, participants who are randomised to the intervention group will be given information about the nested qualitative study by site staff. The information pack will be hosted online and will include a participant information sheet (and easy-read version), participant information video, and demographics questionnaire. Participants will be provided with contact details for the LBU research team should they have any questions about the qualitative study. If after reading all information and asking any questions participants would like to take part in the qualitative study, they will be instructed to complete the online demographics questionnaire (hosted via Microsoft Forms). Information collected in this questionnaire will be used by the LBU team to inform purposive sampling and to invite participants to complete an online consent form (emailed and managed by the LBU team). It will be clear to participants that completing the demographics questionnaire is an **expression of interest only** and they may not be invited to the interview.

Children:

The caregiver information pack will include information about children's interviews. It will also include a children's information sheet and information video for caregivers to share with their child. Caregivers will be instructed to complete a children's demographics questionnaire (hosted via Microsoft Forms) if they are interested in their child participating in the interview study. LBU will use the information collected to inform purposive sampling and the collection of consent as described above. A parent-proxy consent form will be used to collect parental consent for children's participation. It will be clear to caregivers that they **must have parental/guardian responsibility** to complete the children's demographics questionnaire and consent to their child's participation.

SLTs:

SLTs taking part in the feasibility study will be provided with information (hosted online, including an information sheet, information video, and demographics questionnaire) about the qualitative interviews by the LBU research team during site initiation visits. If interested, they will complete the demographics questionnaire which will be used by the LBU team to facilitate purposive sampling and collection of consent in the same way as described above.

Interview-Specific Consent Form

- Purpose**:** Participants and SLTs who agree to participate in interviews will be required to sign a separate consent form specifically for the interviews. Consent for interview participation will be collected and managed by the research team at LBU via an online consent form (via

Microsoft Forms). The information sheet and information video (described above) will explain the nature and purpose of the interviews, the topics covered, participants' ethical rights (including voluntary participation and right to withdraw without consequence) and confidentiality measures in place.

- Children's interviews: A separate parent-proxy consent form will be required for children's participation (also collected online by LBU). The proxy form will explicitly ask parents/carers to involve their child in the decision about whether or not to participate; an age-appropriate information sheet and video will be provided to support parents/carers in having this conversation with their child. These resources will explain to their child what the interviews involve, that their participation is voluntary, their right to withdraw without consequence, and confidentiality measures in place. For children who take part in the interviews, verbal child assent will be collected during an introductory video call with the interviewer after the interviewer has re-shared and explained the children's information sheet. It will be made clear to caregivers that they can only consent to their child participating if they have parental/guardian responsibility for the child.

7.5 The Randomisation Scheme

Randomisation will occur in a 1:1 ratio to one of two study arms using randomly permutated blocks stratified by site via an online system:

1) Control group: Standard NHS speech and language therapy,
2) Intervention group: SuperPenguin in addition to standard NHS speech and language therapy

Blinding will not be implemented in this study due to its design, as participants will be aware of their allocation based on whether they are using the SuperPenguin app alongside usual care.

Only participants randomised to the Intervention group will be invited to take part in the qualitative interviews; the primary aim of the interviews is to evaluate the usability and acceptability of the app.

7.6 Method of Implementing the Allocation Sequence

Randomisation will be completed at Assessment 1 using a web-based system allowing access to authorised users only. Anyone at site delegated randomization duties will be given access to the system.

The user will receive notification of allocation immediately and copies will be emailed to uhdb.superpenguin@nhs.net automatically.

In the event of difficulties with randomisation, the Derby CTSU team should be contacted via uhdb.superpenguin@nhs.net during office hours <>.

7.7 Baseline Data

Each baseline variable included in the data collection process is carefully selected for its relevance to the study's objectives. No variable will be included solely because it is traditionally recorded; instead, only variables that contribute to the analysis of study outcomes will be collected. Baseline data will be collected during Assessment 1.

Participants receiving SuperPenguin as part of the study will complete an assessment to personalise the journey for engaging with content.

In compliance with the General Data Protection Regulation (GDPR) and the Data Protection Act, only data that is directly relevant to the study's objectives will be processed. The Case Report Forms (CRFs) will be designed to collect only the necessary data, with all irrelevant or excessive information excluded. This ensures that the data collection process respects participant privacy and adheres to the legal requirements for handling sensitive information.

Qualitative interviews:
Key demographic information (see Table 3 below) will be collected in online demographics questionnaires hosted via Microsoft Forms as described above. Information collected will be used to inform purposive sampling. Information for participants who are **not** then invited to take part in an interview will be immediately securely deleted. Demographic information collected for interview participants will only be reported in an aggregated form in any outputs arising from the research; it will not be possible to identify any individual participants. All demographic information collected as part of the nested qualitative study will be the responsibility of the LBU team. A Data Protection Impact Assessment (DPIA) has been completed by the LBU team.

Table 3 Demographic information collected as part of qualitative study

Caregivers	Children	SLTs
• Name • Contact details (email, mobile number) • Age • Age of child who is receiving speech and language therapy • Caregiver role (e.g., mother, father, grandparent etc.) • NHS study site where they are participating in the main feasibility study • Gender • Ethnicity • Postcode • Highest level of education • If their child has any need in addition to having a stammer	• Child's name • Child's age • Child's gender • Child's ethnicity • If the child has any need in addition to having a stammer • NHS study site where their caregiver is participating in the main feasibility study • Child's postcode • Caregiver name • Caregiver contact details (email, phone number)	• Name • Contact details (email, mobile number) • Age • Gender • Ethnicity • NHS study site where they work • Years' experience working as an SLT

7.8 Trial Assessments

Participants will be assessed at 4 time points starting from a maximum of 2 months prior to commencing therapy. Assessments include validated patient-reported and therapy outcomes, gathering both qualitative and quantitative data.

Assessments and timepoints are outlined below and in the Schedule of Assessments.

Assessment 1 (maximum of 2 months pre-therapy)
This assessment should be completed a maximum of 2 months prior to starting therapy. It is possible that assessments 1 and 2 could occur the same day or close to each other. After consenting to take part in the study, the following should be completed/collected:

- Demographic information, including age, age of the child, gender, ethnicity, postcode, highest level of education and whether the child has additional needs.
- Email address and/or mobile phone number will be used to facilitate completion of follow-up outcome measures electronically.
- Palin Parent Rating Scale (PPRS)
- EQ5D-3L

Once these are complete, participants will be randomly allocated to either the control or intervention arm.
The Solution Focussed Brief Therapy measures (SFBTs) will then be completed via the eCRF for the control group and within the SPMA for the intervention group AFTER randomisation.

Provision of access to the SuperPenguin App
Those participants randomised to access the app will be given instructions on how to download and access SuperPenguin. Participants will be required to provide their email address and mobile phone number to create an account on the app. These details will be shared with BeneTalk by site staff. If any requests are received from participants in the control group, then access will not be provided.

Follow-up Assessments

All follow-up assessments will be completed and entered into the database by participants electronically (via a link sent to their email address or mobile number) other than the 'Therapy Outcome Measures (TOMs)', which will be collected during therapy and entered into the database by site staff.

For intervention-arm participants, the Solution Focussed Brief Therapy measures (SFBTs) will be collected within the app.

Assessment 2 (at the start of therapy episode)

Following a period of being on the waiting list for therapy (the duration and activities involved in this will follow usual care), participants will commence NHS speech and language therapy - "therapy episode". The following will be completed for all participants before they start therapy:

- Palin Parent Rating Scale (PPRS)
- Solution Focussed Brief Therapy measures (SFBTs)
- EQ5D-3L
- Resource Use Questionnaire
- Therapy Outcome Measures (TOMs)

Assessment 3 (maximum of 4 months post start of the therapy episode or at the end of the therapy episode, whichever is earlier)

The following will be completed for all participants a maximum of 4 months post-start of therapy or at the end of the therapy episode (whichever is earlier):

- Palin Parent Rating Scale (PPRS)
- Solution Focussed Brief Therapy measures (SFBTs)
- EQ5D-3L
- Resource Use Questionnaire
- Therapy Outcome Measures (TOMs)

The following should be completed for Intervention-arm participants only:

- mHealth App Usability Questionnaire (MAUQ)

Assessment 4 (5 months after Assessment 3)

The following questionnaires will be completed 5 months later:

- Palin Parent Rating Scale (PPRS)
- Solution Focussed Brief Therapy measures (SFBTs)
- EQ5D-3L
- Resource Use Questionnaire
- Therapy Outcome Measures (TOMs)

Once participants have completed Assessment 4, they will be considered to have completed the study.

7.9 Schedule of Assessments

Visit			Assessment 1	Assessment 2	Assessment 3	Assessment 4
Timing of visit	**Any time from referral**	**3 months pre-therapy episode**	**0-2 months pre-therapy episode**	**At the start of therapy[1]**	**4 months after start of therapy[2]**	**5 months (+/- 2 weeks) after assessment 3**

Eligibility assessment **(care team only)**	X	X				
Provide study information	X					
Send formal invitation to study		X				
Informed consent			X			
Demographics			X			
Randomisation			X			
PPRS			X	X	X	X
SFBT			X	X	X	X
EQ5D-3L			X	X	X	X
Resource use questionnaire				X	X	X
TOMS				X	X	X
mAUQ[3]					X	
Adverse event assessments				X	X	X

[1] May occur up to 1 week pre-therapy episode

[2] or at the end of the therapy episode, whichever is sooner. May occur up to 1 week after the timepoint.

[3] only for those on the intervention arm

7.10 Qualitative Assessments – Nested Studies

Online semi-structured qualitative interviews (conducted via Microsoft Teams) with caregivers (n = 5-10) and SLTs (n = 5-10) will be nested within the clinical feasibility study to gather in-depth insights on the usability, acceptability, and perceived effectiveness of SuperPenguin, the barriers and enablers to app use, and the acceptability of the trial design. Interviews will also enable real-time feedback regarding the app and feasibility study design to be gathered if participants have any concerns during the course of the study. Online semi-structured interviews (Microsoft Teams) with children (aged 8-12 years) (n = 5-10) will be conducted to explore children's happiness and confidence communicating and their perceptions of receiving help with talking. Interview schedules have been developed by qualitative researchers with experience designing and conducting interviews with children and adults, with input from SLTs and parents/carers of CWS.

Interviews with adults (i.e., caregivers and SLTs) are structured in two parts. First, the usability, acceptability, and perceived effectiveness of the app will be discussed; interview questions have been derived from the domains of the Theoretical Domains Framework (TDF) [29] and the Acceptability Framework [30]. The second part of the interview will focus on exploring perceived acceptability of the trial design. Questions have been informed by [31]. Interviews with children will explore children's views and opinions of talking in usual activities (e.g., how they feel talking in different contexts and how people react to their talking in different contexts) and their views and opinions of receiving help with talking (e.g., do they think they need help, what people do to try and help, and if caregivers speak to them about their talking). The discussions in children's interviews will be supported by a pre-interview activity completed by children with their caregivers in which they make a list (by writing, drawing, taking photos etc.) of all the typical activities they usually do in a week. The list will be used to prompt discussion of talking in different contexts – it will not be used as research data.

Potential caregiver and child participants will be approached with information about the interviews throughout the feasibility study. Sampling will be purposive as described above ("Participants and Setting") (as much as is practically possible) to ensure interviews take place with participants who are waiting for speech and language therapy, participants who are receiving therapy, and participants who have completed therapy. For *adult* participants interviewed while waiting for speech and language therapy, follow-up interviews will also be offered. The aim of follow-up interviews will be to explore the longer-term impact and effect of the app i.e., to explore whether views and perceptions of app usability, acceptability, and effectiveness changed over time.

Similarly, potential SLT participants will be approached throughout the feasibility study with the aim of interviewing both SLTs who are delivering, and who are yet to begin delivering, speech and language therapy to families in the Intervention group. For any SLTs interviewed at the start of the study, follow-up interviews will also be offered to explore if and how their thoughts of the app and the study design have changed over time.
Caregivers (for themselves and/or on behalf of their child) and SLT's will be given a £20 voucher as a thank you gesture and for recompensating their time for participating in the qualitative study interviews.

Analysis will follow the Framework method for analysing qualitative data as described by Gale et al [32]. The Framework method [32] allows for both inductive and deductive coding to be implemented systematically across multiple researchers. Analysis of the acceptability and usability of the app will follow a predominately deductive coding approach informed by the TDF domains [29]. Key themes will be mapped to the TDF domains [29] and Acceptability Framework [30] to determine app usability and acceptability from the perspectives of caregivers and SLTs. Analysis of caregiver and SLT perceptions of the acceptability of trial design and of children's interviews will follow a predominately inductive coding approach to allow for a full exploration of the data.

7.11 Participation Change & Withdrawal

Participants have the right to withdraw their consent at any time, without having to give a reason and without detriment. However, when a participant says they want to stop taking part, the local study team should try to find out exactly which parts of the study the participant wants to stop and which they are happy to continue.

Participants should be given options for reduced participation, as follows:

1. To reduce or stop use of the app but continue with the completion of the questionnaires.
2. To reduce the number of questionnaires completed. (PPRS will be completed as a minimum)
3. To miss a visit(s) but continue in the study.

Any decision to change or reduce their participation in the study should be informed and freely given, and participants retain their right to withdraw fully from the study without detriment to their care. Reasons for participation change will be recorded in the eCRF.

If there is a loss of contact between the local site team and a participant at any follow up time point, then the local team will make a maximum of 2 attempts to contact the participant for that assessment. Up to 2 reminders will be sent for ePRO completion. If neither are successful, attempts will be made to contact the participant again at the next visit, and they will not assume that the participant has withdrawn. Except for the last visit at 5 months post treatment, when the participant will be assumed as lost at follow up.

If a participant contacts the trial staff later and outside of the visit window, then the trial staff will continue with the follow up assessment as per protocol.

If a participant wants to increase their participation after having previously reduced it, the local study team will continue with the assessments as per protocol. The increase in participation will be recorded in eCRF.

For each participant withdrawn, the following documentation will be completed:

- The reason for withdrawal will be recorded, if provided.
- Any follow-up data available up to the point of withdrawal will be collected and recorded in the study database.

- The date of withdrawal and whether the participant withdrew voluntarily or was withdrawn by the investigator will be noted.

Participants who are withdrawn from the study will not be replaced. Their data will still be used in the analysis up to the point of withdrawal, if it is consistent with the study's data analysis plan.

Qualitative interviews:
Participants who agree to take part in the qualitative interviews can withdraw from the interview study at any point without needing to give a reason until two weeks after their interview. They can withdraw by emailing the research team at LBU, after which all email trails will be deleted. The number of participants withdrawing from the interviews (if any) will be recorded.

7.12 End of Trial

The end of trial will be defined as last participant, last visit (Assessment 4). The Clinical Trial Manager will notify the participating sites, HRA and REC within 90 days of the end of trial. The clinical trial report will be written within 12 months of the end of trial.

Premature Stopping of the Trial:

- The study may be prematurely stopped considering the following circumstances. The final decision for stopping the trial will be taken by the independent Trial Steering Committee and the Sponsor:
  - Safety Concerns: If the Class I UKCA Medical Device is found to have a significant safety risk to participants that was not identified at the trial's outset.

8. MEDICAL DEVICE

8.1.1 Description of the device:

The SuperPenguin app is a software-based digital therapy tool (SaMD - Software as a Medical Device) that operates via mobile devices or tablets (SPMA) for caregivers and a web dashboard (SPWD) for clinicians.

Manufacturer	BeneTalk Ltd
Product Name	SuperPenguin
Product Version	1.10
Classification	Class I medical device under the UK Medical Devices Regulations 2002 (SI 2002 No. 618, as amended)
GMDN code	63031 - Mental health/function therapeutic software, screen-viewed
Intended use	SuperPenguin is a mobile application designed to enhance the confidence and self-management skills of carers of children 8 to 12 years old who stammer. It provides personalised educational content after asking AI-generated questions to the carers. It complements, but does not replace, professional Speech and Language Therapy (SLT) support or advice. It is prescribed by trained

	professionals in SLT and intended to be used by carers in out-of-clinic settings, including at home, with basic smartphone proficiency and English literacy.
Target population	The device is intended for caregivers of children who stammer (CWS) aged 8 to 12 years.

8.1.2 The SuperPenguin Mobile Application (SPMA)

Provides activities and therapeutic guidance tailored to the needs of caregivers of children who stammer. Key Features are as follows:

Personalised Journey

After an AI-powered short survey collects onboarding responses (example question: "How familiar are you with the concept of stammering and its impact on children?", the AI selects a tailored set of 3 topics to display on the user's home screen. When the user finishes this set, the list refreshes with new, relevant topics aligned to their evolving needs. This feature allows the app experience to adapt to each user.

Library

The library of available topics is located in the 'Explore' tab in a bottom tab menu. This allows users to explore other content outside of the AI personalised journey.

Family & Friends Access

The user can invite other individuals, such as family members, guardians, or caregivers, to join their child's family and friends network, giving them access to the app. Invitations may be sent as an invite code and an in-app link generated from the app Family page. Once accepted, all linked accounts share the same access entitlements and will see their list of family and inner circle members updated in the 'Family' tab in the bottom tab menu. The users can add or remove a member from their network at any time.

SFBT ("Best hopes") and Progress check-in

At the end of the 'Welcome' topic, the user defines their "best hopes"; the outcome they aim to achieve with SuperPenguin. Periodic check-ins prompt the user to rate their progress with this goal on a 1–10 scale and optionally update the goal. This helps to shape a user's experience into a clear, measurable goal, and through the regular check-ins, they are provided with ongoing encouragement. As part of the intervention, data will be collected on a weekly basis, while outcome data will also be collected at specific timepoints (0-2 months pre-therapy, start of therapy, maximum 4 months after start of therapy or at end of therapy (whichever is sooner) and 5 months after the third assessment) to evaluate the overall effectiveness of the program.

Periodic Assessment & Progress Over Time

Once a month, the user gets an "Assessment topic" within their personalised journey. It uses the validated CarerQoL survey which measures current well-being. Once completed, AI delivers concise, neutral feedback and stores the results in the journal for future reference.

This feature helps track changes over time, tweak support when needed, and evidences the app's impact on the user's journey.

In-Topic User Feedback
Within the topic screens there is a 'feedback' button to allow the users to submit suggestions or alert on any issues. At the end of each topic, a star rating request will appear for the user to evaluate their satisfaction with the topic and share any thoughts. All feedback mechanisms are optional, concise, and non-disruptive. All collected feedback is securely transmitted to a cloud database, where it can be reviewed by the SuperPenguin team.

8.1.3 The SuperPenguin Web Dashboard (SPWD)

Provides professionals involved in speech and language therapy delivery at individual and organisation level to see app usage data through the Web Dashboard which is linked and synchronised with the app. These reports will be used to monitor participant engagement and to follow up during in-person appointments where necessary. Additionally, responses may be reviewed by NHS staff as a way to monitor progress or inform treatment choices, however this is at the discretion of the clinicians. Information in the Web dashboard will be saved in BeneTalk's servers (Google servers located in the EU).

Key features are the following:

- **Direct NHS-Led Account Creation:** NHS staff manually enter carer/child name, email, phone and NHS number, directly into SPWD.
- **Automated Credential Delivery:** After account creation, carers receive login credentials for the SPMA via email or SMS, followed by reminder messages at 3, 5, 10, and 30 days to encourage engagement. In addition, daily in-app push notifications are sent to prompt continued use and reinforce engagement.
- **Detailed Individual Monitoring:** Tracks app usage metrics per user including time spent, session counts, topic completion, and responses.
- **Aggregated Data Monitoring:** This includes topic completion, app downloads and registrations by site or region, referral-to download (referral / account creation vs first-login conversion), 7 and 30 day usage/retention metrics, and progress responses to CarerQoL and SFBT ("Best Hopes") assessments.

Further detail on the content can be found in Appendix 2.

Further information

- No direct contact with body tissues or fluids is required.
- No training is required for SPMA users. Each user is guided through an onboarding process that explains how the app functions and its intended use.
- Speech and Language Therapists (SLTs) will be provided with written deployment guidance and an online training seminar.

- Comparator: Usual care for NHS speech and language therapy without SuperPenguin will be used as the comparator in the trial.
- Medical or Surgical Procedures Involved: There are no invasive medical or surgical procedures. The use of SuperPenguin is purely digital.
- Device exposure: SuperPenguin app will only be used by participants in the intervention arm. The comparator arm will involve usual care for NHS speech and language therapy without the use of the app. Number of devices: Each participant will have access to SuperPenguin Mobile App via a personal device. Each family unit will be limited to one study participant, however other family members may use SPMA as part of the "family & friends access" feature, which will allow family members to create and link new accounts. This is a standard part of the intervention. In this scenario, extended family members will use SPMA without registering as participants in the study.

SuperPenguin (SPMA and SPWD) is a is a UKCA marked Medical Device used within its intended purpose. The device has been classified as Class I medical device under the UK Medical Devices Regulations 2002 (SI2002 No. 618, as amended). The device performs no measuring or monitoring of physiological parameters and therefore falls under Rule 12 (non-invasive devices) of the UK MDR.

8.2 Traceability of the Device

Due to the digital nature of SuperPenguin, traceability will be managed through:

- Software version control to ensure that each participant is using the correct version of the app.
- Access control systems via QR code to monitor and document which participants have used the app.
- Unique user IDs assigned to each family for data tracking purposes.
- Devices (such as smartphones or tablets) provided to participants will be loaned for the duration of the study should a participant not have access to their own smartphone.

8.3 Device Storage, Supply and Accountability

- The SuperPenguin app will be distributed electronically, ensuring that participants in the intervention arm have direct access via mobile devices. The app is available for download via unique QR and access codes provided to each NHS Trust. The codes direct users to the Apple App Store and Google Play if SuperPenguin is not already downloaded on their device and provides access to the app.
- Tablets or smartphones will be loaned to participants who do not have access to compatible devices. Devices loaned to participants will be returned at the end of the trial.
- Data related to the app will be stored on secure servers, in line with data protection regulations.
- Each participant's device usage will be monitored via the app's backend system. This ensures proper engagement with the intervention and adherence to the therapy protocol.

- A software version control log will be updated and maintained by Derby CTSU and be distributed to sites to ensure compliance with using the current version of the Super Penguin app.

8.4 Compliance Monitoring:

The app itself will collect data on usage (see Section 3), which will be reviewed by the study team to assess adherence.

9. ADVERSE EVENT REPORTING

9.1 Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in participants, users or other persons, where or not related to the medical device and whether anticipated or unanticipated.
Adverse Device Effect (ADE)	An adverse event related to the use of a medical device. *NOTE: this definition includes:* • *AEs resulting from insufficient or inadequate instructions for use, deployment, installation, or operation, or any malfunction of the medical device.* • *Any event resulting from user error or from unintentional misuse of the medical device.* • *'Comparator' if the comparator is a medical device.*

Serious Adverse Event (SAE)	An adverse event that led to any of the following:
	• death
	• serious deterioration in the health of the subject, users, or other persons as defined by one of more of the following
	  ○ a life-threatening illness or injury, or
	  ○ a permanent impairment of a body structure or a body function including chronic diseases, or
	  ○ in-patient of prolonged hospitalisation, or
	  ○ medical or surgical intervention to prevent life-threatening illness or injury, or permanent impairment to a body structure of a body function,
	  ○ foetal distress, foetal death, a congenital abnormality, or birth defect including physical or mental impairment.
	• Is otherwise considered medically significant by the investigator

	NOTE: Planned hospitalisation for a pre-existing condition, or a procedure required by the study without a serious deterioration in health, is not considered a SAE.
Serious Adverse Device Effect (SADE)	An adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.
Unanticipated Serious Adverse Device Effect (USADE)	A serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current risk assessment. *NOTE: Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk assessment.*
Device Deficiency	Inadequacy of a medical device with respect to its identity, quality, durability, reliability, usability, safety or performance. *NOTE: This definition includes:* • *Malfunctions, use errors, and inadequacy in the information supplied by the manufacturer including labelling.* • *Device deficiencies related to the medical device or the comparator.*
Serious Health Threat	Signal from any adverse event or device deficiency that indicates an imminent risk of death or a serious deterioration in the health in participants, users or other persons, and that requires prompt remedial action for other participants, users or other persons. *NOTE: this would include events that are of significant and unexpected nature such that they become alarming as a potential serious health hazard or possibility of multiple deaths occurring at short intervals.*

9.2 Operational Definitions for (S)AEs

1. Nature of the Intervention

The SuperPenguin app aims to reduce stress and improve quality of life for caregivers of children who stammer. In this low—risk context, mild mood fluctuations might not necessarily be classified as adverse events (e.g., transient frustration with app content). However, any event that might jeopardise participant safety or wellbeing (e.g., severe emotional distress) should still be noted.

2.End points or study design

Only clinically significant emotional or psychological harm directly linked to the app's usage will be reported as an **AE** or **ADE**. Specifically, this could include events such as increased stress, anxiety, or emotional distress in caregivers using the app (for example from inadequate instructions, user guidance or incorrect or misleading educational/therapeutic content) and any other indirect effects on the child or family dynamics. Since this Class I UKCA Medical Device is not physically invasive, SAEs

are more likely unrelated to the software. However, if an emotional or mental health crisis were triggered or worsened by the Class I UKCA Medical Device content, it would qualify as an SAE.

Minor or expected variations in parental stress or user engagement—captured as part of outcome measures—will not be formally reported as an AE/ADE unless they meet the threshold for adverse event criteria.

3. Not Typically Considered SAEs
- Routine therapy or counselling for an existing condition without serious deterioration.
- Outpatient visits or phone calls for general advice with no severe or unexpected outcome.
- In-app usage without new or worsened health conditions.

4. Reporting to the Sponsor
- Low-level mood changes do not require immediate AE reporting unless they escalate to a clinically significant event.
- The CIP should list foreseeable psychological events (e.g., mild stress) with mitigation plans (e.g., disclaimers, optional referrals).

All relevant events must still be documented in participant notes.

9.3 Recording and Reporting SAEs and USADEs

All AEs, SAEs and device deficiencies must be recorded from the time of randomisation until the last visit (Assessment 4) has been completed.

All (S)AEs and device deficiencies occurring during the duration of the study must be reported to the sponsor by the Principal Investigator or delegated individual at each participating site and documented within the eCRF as per Appendix 1 – Safety Reporting Flow Chart. An assessment will be made by the site research team at each study timepoint to establish if participants have experienced any adverse events. This may be through discussions with the participant, or via a review / notification from the participant's medical records.
The following events are considered reportable:
- Any SAE (whether initially considered device related or not)
- Any device deficiency that might have led to a SAE if:
    - Suitable action had not been taken or
    - Intervention had not been made or
    - If circumstances had been less fortunate.
- New findings/updates in relation to already reported events

When AEs are entered onto the eCRF, the Principal Investigator or delegated individual with appropriate medical training (as determined by the PI) will be alerted and required to categorise each AE and assess for seriousness, causality, and expectedness (SAEs only).

When an AE is identified as being serious (SAE), an additional SAE form will be completed via the eCRF

for reporting to the Sponsor.

If an SAE is deemed related and unexpected, the 'non-CTIMP safety report to REC form' available from the HRA website is to be completed by Derby CTSU and submitted to REC within 15 days of becoming aware of the event. Safety information will be reviewed during TMG/TSC/DMEC meetings.

For each reportable event the following information will be collected:

- Full details of the event, including a diagnosis
- MedDRA coding (system organ class and preferred term)
- Duration (start and end dates)
- Seriousness criteria
- Outcome.
- Action taken.
- Causality (i.e. related to medical device)
- Expectedness

9.4 Assessment of AEs and SAEs

9.4.1 Severity

The investigator should determine the severity of the AE;

- Mild: no interference with daily activities.
- Moderate: moderate interference with daily activities.
- Severe: considerable interference with daily activities (e.g. inability to work).

NOTE: to avoid confusion or misunderstanding the term "severe" is used to describe the intensity of the event, which may be of relatively minor medical significance, and is NOT the same as "serious" which is described in the safety definitions.

9.4.2 Causality

Clinical judgement should be used to determine the relationship between use of the medical device (including the medical-surgical procedure) and the occurrence of each AE;

- Not-related: relationship to the device or procedures can be excluded when:
    - The event is not a known side effect of the product category the device belongs to or of similar devices and procedures;
    - The event has no temporal relationship with the use of the Class I UKCA Medical Device or the procedures;
    - The serious event does not follow a known response pattern to the medical device (if the response pattern is previously known) and is biologically implausible;
    - The discontinuation of medical device application or the reduction of the level of activation/exposure - when clinically feasible - and reintroduction of its use (or increase of the level of activation/exposure), do not impact on the serious event;
    - The event involves a body-site or an organ not expected to be affected by the device

or procedure;
    - The serious event can be attributed to another cause (e.g. an underlying or concurrent illness/ clinical condition, an effect of another device, drug, treatment or other risk factors);
    - The event does not depend on a false result given by the Class I UKCA Medical Device used for diagnosis, when applicable;
    - Harms to the subject are not clearly due to use error;
    - In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious event.
- Unlikely: the relationship with the use of the device seems not relevant and/or the event can be reasonably explained by another cause, but additional information may be obtained.
- Possible: the relationship with the use of the Class I UKCA Medical Device is weak but cannot be ruled out completely. Alternative causes are also possible (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases were relatedness cannot be assessed or no information has been obtained should also be classified as possible.
- Probable: the relationship with the use of the Class I UKCA Medical Device seems relevant and/or the event cannot reasonably explained by another cause, but additional information may be obtained.
- Causal relationship: the serious event is associated with the medical device or with procedures beyond reasonable doubt when:
    - The event is a known side effect of the product category the device belongs to or of similar devices and procedures;
    - The event has a temporal relationship with medical device use/application or procedures;
    - The event involves a body-site or organ that
        - The medical device or procedures are applied to;
        - The medical device or procedures have an effect on;
    - The serious event follows a known response pattern to the medical device (if the response pattern is previously known);
    - The discontinuation of medical device application (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of the level of activation/exposure), impact on the serious event (when clinically feasible);
    - Other possible causes (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment) have been adequately ruled out;
    - Harm to the subject is due to error in use;
    - The event depends on a false result given by the medical device used for diagnosis, when applicable;
    - In order to establish the relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious event.

Assessment of causality must be made by a clinician (usually the Principal Investigator) or a delegated individual with appropriate medical training (as determined by the PI). If a doctor is unavailable, initial reports should be submitted to the Derby CTSU without the causality assessment, but they must be followed up with a medical assessment as soon as possible.

9.4.3 Expectedness

The assessment of expectedness is only required if the event is deemed to be related to use of the medical device.

- Expected: Reaction previously identified and described in the protocol / risk analysis report.
- Unexpected: Reaction not previously described in the protocol /risk analysis report.

The expectedness assessment is delegated to the Principal Investigator or delegated individual with appropriate medical training (as determined by the CI) who will use the current approved protocol and Risk Assessment as reference.

9.5 Expedited reporting

All USADEs must be reported to the REC and the manufacturer.

9.6 Reporting Urgent Safety Measures

If any urgent safety measure is taken the research team should inform the Derby CTSU within 24 hours using the Derby CTSU's safety incident reporting form. The Derby CTSU will inform the REC and participating sites of the measures taken and the circumstances giving rise to those measures within 3 days on implementation of the urgent safety measure.

10. DATA HANDLING

A Data Management Plan will be written with more detail on the data handling for the study, the following section serves as a summary.

10.1 System and Compliance

An electronic software platform will be used to store participant study data. Data entry will be via a web-based, fully validated system, compliant with 21 CRF Part 11; Electronic records; Electronic signatures and EU Commission Directive 2005/28/EC with comprehensive audit trials. Derby CTSU will be responsible for database build and system validation. Data will be hosted externally according to General Data Protection Regulation guidance.

Entry into the database will be performed by site staff transcribing from medical records and questionnaires and ePRO directly into the database.

10.2 Source Data

Source data is the term used to describe the place where data are first recorded. This will include medical records containing key eligibility and demographic data, as well as study documents including the consent form and questionnaires which will be documented on a site source data location list. The eCRF may also serve as source data if data is entered directly into the system.

Source data must be kept in line with the archiving requirements outlined in the 'Archiving' section. Physical copies of source data should contain a subject identifier on each page where possible. If original documentation is transferred from the site, it is necessary for the trial site to retain a copy to ensure that the Principal Investigator can provide access to the source documents to a monitor, auditor, or regulatory agency (appropriate access will be granted to eCRFs based upon the requirements).

10.3 Data Workflow

The DCTSU Data Management (DM) team will design the database to capture the clinical data in accordance with the best principles of clinical data management and the relevant SOP on Case Report Form and Database Selection, Development & Release developed by Derby CTSU.

Data will be entered into the eCRF at the site or by participants via ePRO. During data entry, validation checks will automatically be performed on the data to ensure accuracy and consistency according to the Data Validation Plan. All data queries generated as a result of these checks will be available for resolution online. After data entry is complete, all data queries have been resolved and medical coding is completed, the database will be locked and released for statistical analysis. A copy of the trial database will be filed in the eTMF, and if required, copies will be provided to the Sponsor and Chief Investigator.

The MedDRA coding dictionary will be used to code adverse events. When an event is entered into the database, the system will attempt to auto-code the reported term. If the term is able to be auto-coded, the term can be approved by the individual delegated to perform coding. If the term is not able to be auto-coded, the delegated individual must manually code the term. More detail around coding will be recorded in the Data Management Plan.

All clinical data will be collected, stored, processed, and archived in accordance with the Data Management Plan for this trial and in line with the relevant SOPs on Data Entry, Data Closeout Activities and Archiving developed by the Derby CTSU and any relevant legislation.

10.4 Data Access and Security

Access to the trial database will be restricted by role-based permission to authorised trial personnel. Users will be suitably trained on the system prior to being granted access. Individual user accounts will be password protected and will not be shared between members of the trial team.

Access will be granted to authorised representatives from the sponsor, trial team and the regulatory authorities to permit trial-related monitoring, audits and inspections. The purpose of these inspections is to verify and corroborate the data collected on the case report forms. In order to do this

direct access to medical or clinic records may be necessary. The CI / PI must inform the Sponsor if they are notified of a forthcoming audit by the IEC/IRB or regulatory authorities.

Qualitative interviews:
As for the main feasibility study, a separate full data management plan has been written detailing data handling for the nested interview study. The plan is summarised below:

The interview study will produce the following sources of data:

- Digital consent forms (collected via Microsoft Forms)
- Demographic details (collected via Microsoft Forms)
- Audio/visual recordings of online interviews (made using Microsoft Teams)
- Automated transcriptions of interviews (made using Microsoft Teams)
- Anonymized transcripts of interviews stored as text files
- Participant contact details (names, mobile numbers and email addresses)

Participant demographics and contact details will be collected to facilitate recruitment to the qualitative study. Information will be collected via Microsoft Forms as recommended by LBU. Information will be downloaded as Excel Files and then deleted from Microsoft Forms as soon as possible. For participants **not** invited to interview, these details will be immediately securely deleted. For participants who are invited to interview, contact details and potentially identifiable information will be stored only as long as necessary to facilitate recruitment (anticipated end date: 31st July 2027). It will be stored in a secure password-protected University SharePoint site as recommended by LBU away from other research data. It will only be accessible by members of the LBU research team. When recruitment is complete, all demographic information will then be anonymised and aggregated; it will not be possible to identify any individuals.

Informed consent will be gathered online using Microsoft Forms (a secure online questionnaire platform recommended by LBU). Consent forms will be downloaded from Microsoft Forms as Excel files and then deleted from Microsoft Forms as soon as possible. The downloaded Excel files will be stored in secure password-protected University SharePoint site and kept for only as long as is necessary in-line with LBU research data policy (6 years).

Audio/visual recordings and automated transcripts of online interviews will be downloaded from Microsoft Teams and transferred to a secure password-protected folder University SharePoint site as soon as possible after the interview. The original files will then be immediately deleted from Teams and from any local download folders. Recordings will be kept only as long as is necessary to support the checking of transcripts and analysis of data. They will be deleted when analysis is complete (anticipated study end date: 31st July 2027). Automated transcripts will be checked for accuracy by the interviewer and any potentially identifiable information (e.g., participant names) will be removed. Anonymized transcripts will be stored as text files in a secure password-protected University SharePoint site. Following completion of the study they will be deposited in the LBU research repository - "LBU Thesis and Research Data Repository" - to support verification of findings.

Only Leeds Beckett University computers will be used to analyse identifiable data and only members of the research team at LBU will have access to identifiable data gathered in the qualitative interviews. Where research team members from other sites and PPIE representatives are involved in analysis, they will only have access to anonymised data. A Data Protection Impact Assessment (DPIA) has been completed to ensure the safe and appropriate storage of potentially identifiable information.

10.5 Archiving

At the end of the trial, following completion of the end of trial report, the Derby CTSU will oversee the secure archiving of all centrally held trial related documentation for a minimum of 5 years.
At the end of the defined archive period arrangements for confidential destruction will be made. It is the responsibility of each PI to ensure that data and all essential documents relating to the trial are retained securely for a minimum of 5 years after the end of trial, and in accordance with national legislation.

The Derby CTSU will notify sites when trial documentation held at sites may be archived and then destroyed. All archived documents must continue to be available for inspection by appropriate authorities upon request.

11. STATISTICS AND DATA ANALYSIS

11.1 Sample Size Calculation

The sample size calculation is based on the hypothesis testing approach described by Lewis et al [33]. In this study, randomisation rate is defined as the proportion of participants randomised out of all the caregivers that have been approached.

The approach frames this as a hypothesis test, where the lower threshold (20%) represents an unacceptably low randomisation rate and the upper threshold (33%) represents an acceptable rate. The sample size is calculated to ensure 90% power to detect that the randomisation rate is above the lower threshold if the true rate is at or above the acceptable threshold, using a one-sample proportion test with continuity correction.

Based on this, 102 caregivers will be approached and assuming a 33% randomisation rate, this would result in 34 participants being randomised. (17 per arm).

Sample size was calculated using STATA Version 17.0.

Qualitative interviews:
A description of the sampling strategy and target sample size for the qualitative interviews is included in the section “Participants & Setting”.

11.2 Planned Recruitment Rate

On average, 7 caregivers are eligible each month. Assuming 90% to be approached (e.g.6/month) and 33% randomisation rate, then 2 will be randomised per month for a total duration of 9 months. The recruitment projections are based on 3 recruiting sites, slow recruitment start in each site, recruitment fatigue, and opening of sites monthly.

11.3 Statistical Analysis

11.3.1 Summary of Demographic/Baseline Data and Flow of Patients

Descriptive statistics will be presented to summarise the distribution of demographic and baseline variables, medical history and concomitant medications across each of the randomisation groups. The continuous baseline variables (i.e. age) will be reported with means & 95% confidence intervals (95% CI), if shown to be normally distributed, using a normality plot, otherwise will be reported with medians & Interquartile Ranges (IQR). The categorical variables (i.e. gender, ethnicity, NHS Trust, socioeconomic status/indices of deprivation, highest level of education) will be reported with frequencies & percentages.

A CONSORT (Consolidated Standards of Reporting Trials) flow diagram will be created to show the recruitment process and participant progression through the trial. The diagram will include the following steps:

- Assessed for eligibility (number of caregivers assessed for inclusion),
- Frequency of each reason for not being eligible,
- Eligible caregivers identified
- Caregivers approached,
- Excluded before consent (and the frequency of each reason for exclusion),
- Caregivers consented,
- Excluded before randomisation (and the frequency of each reason for exclusion),
- Total number of participants randomised,
- Participants allocated to each randomisation group,
- Participants who received the allocated treatment,
- Participants that did not receive each allocated treatment,
- Participants completed each follow up assessment (and the frequency of each reason for non-completion) for each analysis group,
- Participants analysed for each analysis group,
- Participants not analysed (and the frequency of each reason for not being analysed) for each analysis group.

Demographic information collected and managed by LBU as part of the qualitative study is described above in “Baseline Data”.

11.3.2 Primary Outcome Analysis

Descriptive statistics will be used to describe all feasibility outcomes and will be presented by arm and the total. Frequencies and percentages with the 95% Confidence Intervals (CIs) using the Exact Binomial method, will be presented.

The eligibility rate will be defined as the proportion of eligible caregivers out of the total number of caregivers screened.

The approach rate will be defined as the proportion of eligible caregivers who were approached for participation.

The consent rate will be defined as the proportion of caregivers for whom consent was provided out of those approached.

The randomisation rate will be defined as the proportion of caregivers randomised out of the number of caregivers that were approached. Reasons for non-randomisations will be described using frequencies and percentages. The proportion of caregivers randomised relative to the expected sample size will also be presented.

Any withdrawals and reasons for withdrawal and changes of participation will be summarised as frequencies and proportions.

The completion of outcomes is defined as the proportion of participants completing all assessments of PPRS, SFBT and MAUQ (only the intervention arm) at the appropriate visits and TOMs being completed by clinicians at all timepoints. Completion will also be evaluated individually for each assessment. This will be described in the ITT (Intention-to –Treat) population.

SuperPenguin will collect usage data, which will be summarised using descriptive statistics, where the mean (standard deviation), median (interquartile range) will be presented for any quantitative data, and frequencies and percentages will be presented for any qualitative data. This will be described in the intervention arm only within the ITT population.

The SuperPenguin app adherence is defined as the proportion of participants who have downloaded the SuperPenguin app and completed one topic. This will be described in the intervention arm within ITT population.

The completion of participation at 5 months post therapy is defined as the proportion of participants who have completed all assessments at 5 months post therapy (PPRS and SFBT) and TOMs completed by the clinician. This will be described in the ITT population.

The treatment allocation adherence is defined as the proportion of caregiver participants who have attended all NHS speech and language therapy sessions and downloaded the SuperPenguin app and completed one topic (intervention arm only). This will be described in the ITT population.

As these are feasibility outcomes no statistical tests will be conducted.

11.3.3 Progression Criteria

The stop-go criteria for progression to a definitive RCT are described in Section 4.1.

11.3.4 Secondary Outcome Analysis

Caregiver confidence will be assessed using PPRS which includes scores from the three factors:
(1) Impact of Stuttering of Child
(2) Severity of Stuttering and Impact on the Parents
(3) Parent's Knowledge and Confidence in Managing the Stuttering

Descriptive statistics (means and standard deviation and 95% CIs or median and interquartile range as appropriate) will be presented for each arm at each timepoint and the change from 0-2 months pre-therapy for each factor. The scores will also be displayed graphically over time.

This will be analysed in the ITT population.

SFBT

This will be summarised using descriptive statistics at each timepoint and any change from 0-2 month pre-therapy by arm, where the mean (standard deviation) or median (interquartile range) as appropriate will be presented for any quantitative data and frequencies and percentages will be presented for any qualitative data.

This will be analysed within the ITT population.

TOMS

Therapy Outcome Measures (TOMs) that are assessed by the clinician includes scores from four domains

(1) Impairment
(2) Activity
(3) Participation
(4) Wellbeing/Stress

Scores for each domain will be summarised using mean (standard deviation) or median (interquartile range) at each timepoint and change from start of therapy by arm. The scores will also be displayed graphically over time.

This will be analysed in the ITT population.

MAUQ

Usability will be assessed using the MAUQ questionnaire. The average score will be summarised for all participants in the intervention arm in the ITT population using mean (standard deviations) or median (interquartile ranges) as appropriate.

This will be analysed in the ITT population.

Safety

Safety will be assessed in both arms of the study. For participants in the intervention arm, this will include device-related safety data, including device deficiencies, Adverse Device Effects (ADEs), Serious Adverse Device Effects (SADEs) and Unanticipated Serious Adverse Device Effects (USADEs). Both arms will collect general adverse events (AEs) and serious adverse events (SAEs) and will be recorded to monitor overall safety. Safety data will be summarised using descriptive statistics, including frequencies and proportions and individual listings will be provided as appropriate.

This will be analysed in the Safety Population (SP).

Qualitative Assessments

The semi-structured interviews will be analysed as described above in the "Qualitative Assessments - Nested Studies" section.

11.3.5 Subgroup Analyses

No subgroup analyses will be conducted.

11.3.6 Adjusted analyses

As this is a feasibility study, no adjusted analyses will be conducted.

11.3.7 Interim analysis and criteria for the premature termination of the trial

No interim analyses will be conducted.

The Sponsor may suspend or prematurely terminate either the entire study, or the study at an individual site, for significant reasons that must be documented (e.g. an unacceptable risk to participants or serious repeated deviations from the protocol/ regulations). If this occurs the Sponsor shall justify its decision in writing and will promptly inform any relevant parties (i.e. participants, investigators, participating sites, REC, regulatory bodies).

11.4 Analysis Groups

Intention to Treat (ITT) population: Any participants that have been randomised to either the control or interventional arm, regardless of whether they complied with the trial allocation.

Safety Population (SP): Any participants that have been randomised and have received at least one component of the allocated treatment (NHS speech and language therapy session or downloaded the SuperPenguin app).

11.5 Procedure(s) to Account for Missing or Spurious Data

As this is a feasibility and descriptive study, any missing data will be excluded from the analyses and no imputations or other methods for handling missing data will be performed. The primary aim is to explore feasibility and descriptive outcomes rather than draw definitive conclusions.

11.6 Health Economic Evaluation

Health economic data will be collected to both inform the approach to a later definitive trial and populate an early exploratory health economic model. The health economic analysis will compare quality of life (gathered using EQ5D-3L) and resource use in the intervention and control arms over the duration of the trial. Missing data will be handled using multiple imputation. Quality of life will be calculated using area under the curve and will be adjusted for baseline values. Resource use will be collected using an adapted version of the Client Service Receipt Inventory [34] and will include health and social care perspective and a societal perspective. Health and social care resource use will be costed using the NHS National Cost Collection and the Unit Costs of Health and Social Care. A mean cost will be derived after adjusting for baseline variables. Mean cost and mean quality of life will be used to estimate the cost-utility of the intervention versus the control arms. Sub-group analysis will be presented by site.

12. MONITORING, AUDIT & INSPECTION

Monitoring and source data verification, where applicable, will be conducted by the Derby CTSU according to the study monitoring plan. The extent and nature of monitoring will be determined by the level of risk, which considers study objectives, purpose, design, complexity, number of patients and sites, and endpoints. Monitoring will be a combination of central, remote and on-site monitoring activities visits.

The Investigator(s) must ensure that source documents and other documentation for this study are made available to study monitors, the REC or regulatory authority inspectors. Authorised representatives of the Sponsor and competent authority may visit the participating sites to conduct audits/ inspections.

13. ETHICAL AND REGULATORY CONSIDERATIONS

13.1 Peer review

This study has been peer reviewed as part of the NIHR Invention for Innovation application process.

13.2 Public and Patient Involvement

Patients, carers, and members of the public will be actively involved throughout the research process via a Public Advisory Group (PAG) and a Young Person's Advisory Group (YPAG).

- **Design of the Research**: The PAG and YPAG will provide feedback on the study design, app development, and participant materials to ensure they address user needs
- **Management of the Research**: Both groups will meet regularly to advise on key aspects, such as app usability, participant recruitment strategies, and inclusivity.
- **Undertaking the Research**: The advisory groups will review participant-facing materials, including consent forms, questionnaires, and app content, to ensure clarity and appropriateness.
- **Analysis of Results**: The groups will contribute to interpreting findings, offering perspectives based on lived experience to ensure results reflect the needs of CWS and their families.
- **Dissemination of Findings**: Members of the PAG and YPAG will help develop and provide lay dissemination messaging.

13.3 Research Ethics Committee (REC) & Regulatory Compliance

The study will be conducted in compliance with the approved protocol, the Declaration of Helsinki, the principles of Good Clinical Practice (GCP) Medical Devices Regulations 2002 and ISO 14155:2020.

The protocol and all related documentation (e.g. informed consent form, participant information sheet, questionnaires) have been reviewed and received approval by a Research Ethics Committee (REC) and the Health Research Authority (HRA). The nested qualitative interview study has also been reviewed and approved by the LBU REC.

The investigator will not begin any participant activities until approval from the HRA and REC has been obtained and documented. Any additional requirements imposed by the REC, HRA and regulatory authority shall be followed. Participating sites must confirm their capacity & capability to conduct the study via their Research and Development (R&D) department, before the Sponsor (via the Derby CTSU) issues the site "Green Light" to commence recruitment. All documentation and correspondence must be retained in the trial master file/ investigator site file.

Amendments that require approval from the relevant review bodies will not be implemented until approvals are granted (except for those necessary to reduce immediate risk to participants), as per Section 13.9. Participating sites will have 35 days to object to any amendment submitted for their review before it is implemented.

Derby CTSU is responsible for notifying the REC of the end of trial (see Section 7.10) within 90 days, (15 days if the study ends prematurely). Within one year of the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC.

13.4 Protocol Compliance/ Non-Compliance Reporting

The Principal Investigator at each site is responsible for ensuring that the study is conducted in accordance with the procedures described in this protocol. Prospective, planned deviations and/or waivers to the protocol are not acceptable, however accidental deviations (non-compliances) may happen and as such these must be recorded. Non-compliances may be identified by the site team, or by the Derby CTSU during monitoring of the trial.

All non-compliances must be recorded in the eCRF and categorised as minor or major, and reviewed against serious breach criteria. They will be reviewed during monitoring of the trial and/or during Trial Management Group meetings. Non-compliances which are found to frequently recur are not acceptable, will require immediate action, and could potentially be classified as a serious breach. For all major non-compliances, corrective and preventative actions (CAPA) should be documented in line with Derby CTSU procedures.

Principal investigators may be disqualified for the following:

- Fraud & misconduct
- Severe lack of PI oversight
- Lack of response to findings arising from monitoring and/or audits
- Constant non-compliance and a lack of action once identified.

13.5 Notification of Serious Breaches to GCP and/or the protocol

A "serious breach" is a departure from the protocol, Sponsor procedures (i.e. SOPs), or regulatory requirements which is likely to effect to a significant degree –

(a) The safety or physical or mental integrity of the subjects of the trial; or
(b) The scientific value of the trial.

If a serious breach is identified, PI must complete the ***Non-CTIMP Notification of a Serious Breach*** – *CTU/FRM/015* and submit to the Derby CTSU within 1 working day. The report will be reviewed and actioned by the Derby CTSU according to ***Non-Compliance and Serious Breaches*** - *CTU/SOP/014*.

13.6 Data Protection and Patient Confidentiality

The trial will be conducted in accordance with the Data Protection Act 2018. The investigator must ensure that participant's anonymity is maintained throughout the study and following completion of the study. Participants will be identified on all trial specific documents (except for the informed consent form and enrolment log) only by the participants study specific identifier (and initials if deemed necessary). This identifier will be recorded on documents and the database. The Investigator Site File will hold an enrolment log detailing the study specific identifier alongside the names of all participants enrolled in the study.

All documents will be stored securely with access restricted to trial staff and authorised personnel.

Anonymised data (age, gender, ethnicity) will be collected on the study database for potential participants who are screened but not consented, in line with CONSORT guidelines.
Potential participants will confirm agreement (consent to contact) for the site staff to enter their email and/or mobile number in the database to enable a link to the electronic consent form to be sent to them via email or SMS. This confirmation will be documented in the participant electronic health records.

All data collected from participants will be stored on the study database with controlled access as detailed in Section 10.

The Sponsor will act as the custodian of the data generated in the trial.

13.7 Financial and Other Competing Interests for the Chief Investigator, Principal Investigators at Each Site and Committee Members for the Overall Trial Management

Derby CTSU has no competing interests for this study.
Leeds Beckett University has no competing interests for this study
RM is the Chief Investigator and an employee of BeneTalk Ltd (study sponsor). He also owns company shares. RM receives no additional personal fees related to this trial. He declares no other financial or non-financial competing interests.
All members of the trial oversight committees will be required to sign and abide by the TOR/Charter to declare any competing interests

13.8 Indemnity

The Sponsor has ensured appropriate insurance and indemnity to meet any potential legal liability arising from the management of this research. Coverage is in line with regulatory requirements and includes risks associated with trial oversight, data management, and participant safety monitoring.

13.9 Amendments

If changes to the study are requested, these must be discussed with the sponsor, who is responsible for deciding if an amendment is required and if it should be deemed substantial or non-substantial in conjunction with the IRAS/HRA amendment tool categorisation.

The HRA Amendment Tool will be completed according to the latest guidance from the HRA. All amendments will be submitted to the relevant review bodies (REC, HRA) for approval, indicated by the Amendment Tool. Amendments will only be implemented after all required approvals have been obtained.

Amendments will be circulated to sites for confirmation of continued capacity & capability depending on whether they are Category A, B, or C. Sites will be given 35 days to raise an objection to the amendment before it will be implemented.

13.10 Access to Final Trial Dataset

The Sponsor will act as Data Controller for the study data. Derby CTSU and Leeds Beckett University will act as Data Processors, managing study data throughout the study. At the end of the trial, Derby CTSU will provide the full dataset to the Sponsor. Requests for data will be managed by the Sponsor, who retains ownership of the data.

14. DISSEMINATION POLICY

The protocol will be registered on the ISRCTN registry, and the results will be made publicly available. Any publication, conference abstract, lay summary or media release must receive Sponsor approval and will exclude proprietary technical details or source-code

The Chief Investigator, supported by Derby CTSU will lead on the dissemination plan outlined below. All publications will be reviewed and approved by the Sponsor and any party to whom the Sponsor has any legal obligations to give notice of publication.

A final trial report will be written and provided to the NIHR as outlined in the funding agreement. The report will also be provided to the REC who approved the study within 12 months of the end of the trial.

A full, separate dissemination plan has been created and shared with PPI co-applicants and will serve as a living guide to dissemination activities and evaluation throughout the project. PPI contributors will be invited to collaborate on dissemination activities throughout, including being authors on journal articles, contributing to the creation of lay summaries/reports, and attending academic conferences. Plans to generate and measure impact, as well as a timeline and evaluation plan for dissemination activities, are embedded throughout the separate dissemination plan.

In brief, dissemination activities aim to: (1) contribute to the transparent reporting and documentation of the development of the app supporting the design of a future definitive RCT; (2) raise awareness of the app among key users and policy makers; (3) raise awareness of health inequalities and methods for addressing these; and (4) contribute to wider research within the fields of stammering support, implementation science, and SLCN. Target audiences include key stakeholders within the NHS (including SLTs, service managers, and policy makers), PPI collaborators, families of CWS, stammer charities and networks, and researchers and academics working in related fields.

A range of dissemination methods will be used to ensure reach and accessibility to the range of target audiences. These will include, for example: (1) journal articles with accompanying lay summaries, easy-read versions, and video/visual abstracts; (2) online webinars and discussions targeted at NHS stakeholders and charities (e.g., via National Stammering CEN); (3) lay online materials (e.g., a You Voice piece for the STAMMA website); (4) email updates and newsletters for PPI collaborators and

study participants, a summary of results for those participants who provide optional consent to receive this at the end of the study; and (5) presenting and networking at a range of academic conferences.

14.1 Authorship Eligibility Guidelines and any Intended Use of Professional Writers

Authorship of the final trial report and subsequent publications will be assigned using The International Committee of Medical Journal Editors (ICMJE) defined criteria.

15. REFERENCES

1. Smith, A., & Weber, C. (2017). How Stuttering Develops: The Multifactorial Dynamic Pathways Theory. *Journal of Speech, Language, and Hearing Research*, *60*(9), 2483–2505. https://doi.org/10.1044/2017_JSLHR-S-16-0343

2. Yairi, E., & Ambrose, N. (2013). Epidemiology of stuttering: 21st century advances. *Journal of Fluency Disorders*, *38*(2), 66–87. https://doi.org/10.1016/j.jfludis.2012.11.002

3. Bernard R. (2019). *Suffering in Silence: Access to specialist services for children who stammer*. Accessed 13th February, 2025. https://actionforstammeringchildren.org/wp-content/uploads/2024/09/Suffering-in-silence-addendum_WEB.pdf

4. Onslow, M., & O'Brian, S. (2013). Management of childhood stuttering. *Journal of Paediatrics and Child Health*, *49*(2), E112–E115. https://doi.org/10.1111/jpc.12034

5. Adriaensensa, S., & Struyf, E. (2018). The importance of self-perceptions and perceptions of others on stuttering in adolescence. Going beyond the iceberg analogy. *Proceedings of the 3rd International Conference on Stuttering*. 59-68.

6. Campbell, P. (2019). *Stammering Pride and Prejudice*. J & R Press Limited.

7. Millard, S. K., Murphy, S., Barton, G., Leathersich, M., Mills, G., Rixon, L., Shepstone, L., Sims, E., & Joffe, V. (2022). Evaluating Palin Stammering Therapy for School Children (Palin STSC 8–14): Protocol for a feasibility randomised controlled trial comparing Palin STSC (8–14) with usual treatment. *Pilot and Feasibility Studies*, *8*(1), 210. https://doi.org/10.1186/s40814-022-01158-1

8. Simpson, S., Campbell, P., & Constantino, C. (2021). Stammering: Difference not defect. *Redefining Stammering.* Accessed 13th February, 2025. https://www.redefiningstammering.co.uk/stammering-difference-not-defect/

9. Rezaeian, M., Akbari, M., Shirpoor, A. H., Moghadasi, Z., Chitsaz zadeh, N., Nikdel, Z., & Hejri, M. (2020). Anxiety, Social Phobia, Depression, and Suicide among People Who Stutter; A Review Study. *Journal of Occupational Health and Epidemiology*, *9*(2), 98–109. https://doi.org/10.29252/johe.9.2.98

10. Guttormsen, L. S., Yaruss, J. S., & Næss, K.-A. B. (2021). Parents' Perceptions of the Overall Impact of Stuttering on Young Children. *American Journal of Speech-Language Pathology*, *30*(5), 2130–2142. https://doi.org/10.1044/2021_AJSLP-20-00113

11. Iverach, L., & Rapee, R. M. (2014). Social anxiety disorder and stuttering: Current status and future directions. *Journal of Fluency Disorders*, *40*, 69–82. https://doi.org/10.1016/j.jfludis.2013.08.003

12. Millard, S. K., Zebrowski, P., & Kelman, E. (2018). Palin Parent–Child Interaction Therapy: The Bigger Picture. *American Journal of Speech-Language Pathology*, *27*(3S), 1211–1223. https://doi.org/10.1044/2018_AJSLP-ODC11-17-0199

13. Brignell, A., Krahe, M., Downes, M., Kefalianos, E., Reilly, S., & Morgan, A. (2021). Interventions for children and adolescents who stutter: A systematic review, meta-analysis, and evidence map. *Journal of Fluency Disorders*, *70*, 105843. https://doi.org/10.1016/j.jfludis.2021.105843

14. Sander, R. W., & Osborne, C. A. (2019). Stuttering: Understanding and Treating a Common Disability. *American Family Physician*, *100*(9), 556–560.

15. Langevin, M., Packman, A., & Onslow, M. (2010). Parent perceptions of the impact of stuttering on their preschoolers and themselves. *Journal of Communication Disorders*, *43*(5), 407–423. https://doi.org/10.1016/j.jcomdis.2010.05.003

16. Millard, S. K., Edwards, S., & Cook, F. M. (2009). Parent-child interaction therapy: Adding to the evidence. *International Journal of Speech-Language Pathology*, *11*(1), 61–76. https://doi.org/10.1080/17549500802603895

17. Harris, V., Onslow, M., Packman, A., Harrison, E., & Menzies, R. (2002). An experimental investigation of the impact of the Lidcombe Program on early stuttering. *Journal of Fluency Disorders*, *27*(3), 203–214. https://doi.org/10.1016/S0094-730X(02)00127-4

18. Jones, M., Onslow, M., Packman, A., Williams, S., Ormond, T., Schwarz, I., & Gebski, V. (2005). Randomised controlled trial of the Lidcombe programme of early stuttering intervention. *BMJ*, *331*(7518), 659. https://doi.org/10.1136/bmj.38520.451840.E0

19. Sjøstrand, Å., Kefalianos, E., Hofslundsengen, H., Guttormsen, L. S., Kirmess, M., Lervåg, A., Hulme, C., & Næss, K.-A. B. (2021). Non-pharmacological interventions for stuttering in children six years and younger. *Cochrane Database of Systematic Reviews*, *2021*(9). https://doi.org/10.1002/14651858.cd013489.pub2

20. Constantino, C. D. (2023). Fostering Positive Stuttering Identities Using Stutter-Affirming Therapy. *Language, Speech, and Hearing Services in Schools*, *54*(1), 42–62. https://doi.org/10.1044/2022_LSHSS-22-00038

21. Sisskin, V. (2023). Disfluency-Affirming Therapy for Young People Who Stutter: Unpacking Ableism in the Therapy Room. *Language, Speech, and Hearing Services in Schools*, *54*(1), 114–119. https://doi.org/10.1044/2022_LSHSS-22-00015

22. Millard, S. K., & Davis, S. (2016). The Palin Parent Rating Scales: Parents' Perspectives of Childhood Stuttering and Its Impact. *Journal of Speech, Language, and Hearing Research*, *59*(5), 950–963. https://doi.org/10.1044/2016_JSLHR-S-14-0137

23. Plexico, L. W., & Burrus, E. (2012). Coping with a child who stutters: A phenomenological analysis. *Journal of Fluency Disorders*, *37*(4), 275–288. https://doi.org/10.1016/j.jfludis.2012.06.002

24. Action for Stammering Children (2024). *Specialist support for childhood stammering in England*. Accessed 29th May 2025. https://actionforstammeringchildren.org/stammering-support-in-england-a-call-to-action/

25. Bercow, J. (2018). *Bercow: Ten Years On – An independent review of provision for children and young people with speech, language and communication needs in England*. Accessed 17 February, 2025, from http://www.bercow10yearson.com/

26. Baumel, A., Muench, F., Edan, S. and Kane, J.M. (2019) 'Objective user engagement with mental health apps: systematic search and panel-based usage analysis', *Journal of Medical Internet Research*, 21(9), p. e14567. https://doi.org/10.2196/14567

27. Richards, D. *et al.* (2020) 'A pragmatic randomised waitlist-controlled effectiveness and cost-effectiveness trial of digital interventions for depression and anxiety', *NPJ Digital Medicine*, 3, article 85. https://doi.org/10.1038/s41746-020-0293-8

28. Avery, K.N.L. *et al.* (2017) 'Informing efficient randomised controlled trials: exploration of challenges in developing progression criteria for internal pilot studies', *BMJ Open*, 7(2), p. e013537. https://doi.org/10.1136/bmjopen-2016-013537

29. Michie, S., Johnston, M., Abraham, C., Lawton, R., Parker, D., & Walker, A. (2005). Making psychological theory useful for implementing evidence based practice: a consensus approach. *BMJ Quality and Safety, 14*(1), 26-33. https://doi.org/10.1136/qshc.2004.011155.

30. Sekhon, M., Cartwright, M., & Francis, J.J. (2017). Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. BMC Health Services Research, 17(1), 1-13, https://doi.org/10.1186/s12913-017-2031-8

31. O'Cathain, A., Hoddinott, P., Lewin, S., Thomas, K.J., Young, B., Adamson, J., Jansen, Y.J.F.M., Mills, N., Moore, G., & Donovan, J.L. (2015). Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. Pilot and Feasibility Studies, 1(1), 1-13. https://doi.org/10.1186/s40814-015-0026-y

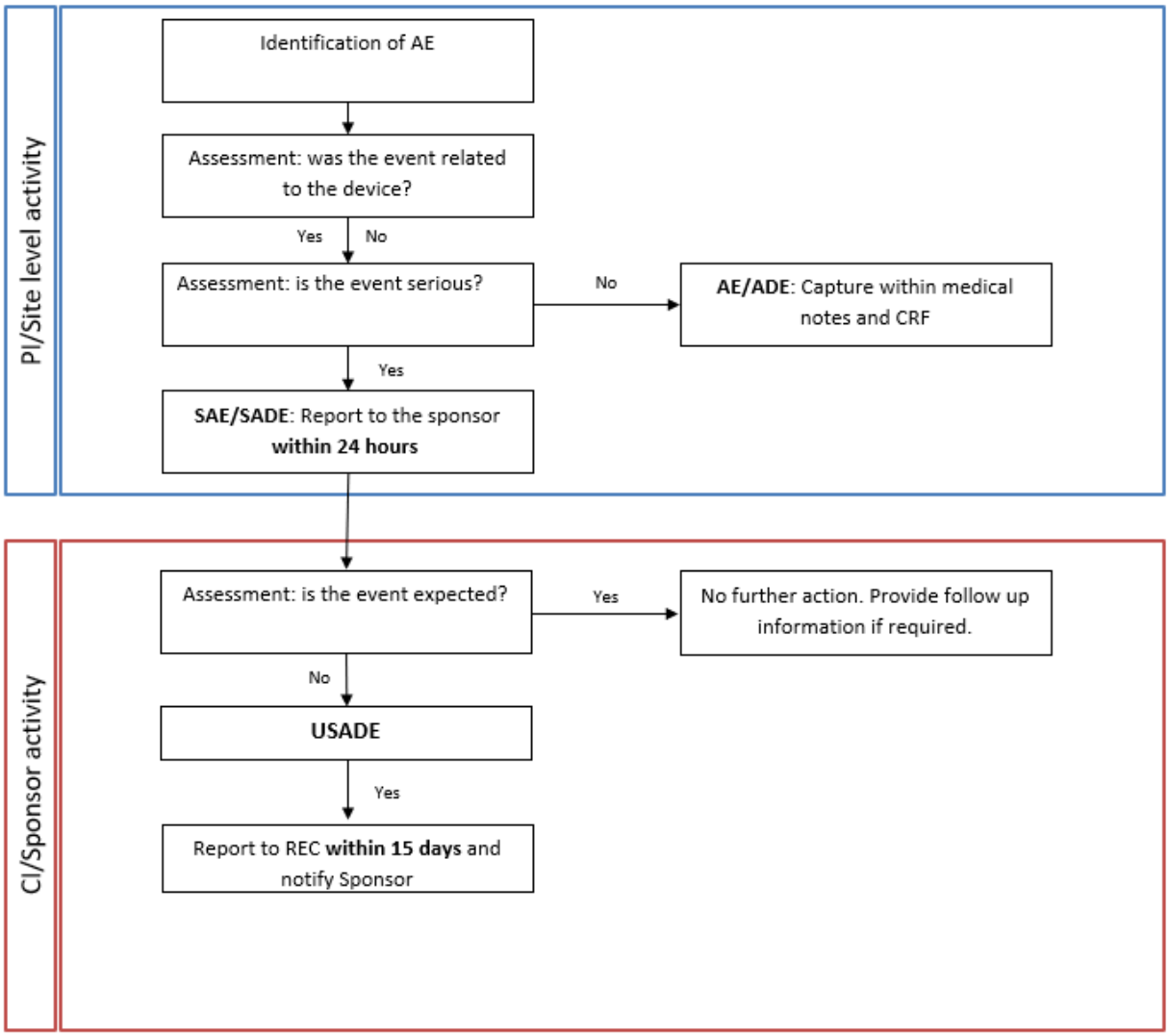
32. Gale, N.K., Heath, G., Cameron, E., Rashid, S., & Redwood, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Medical Research Methodology, 13(1), 1-8. https://doi.org/10.1186/1471-2288-13-117

33. Lewis, M., Bromley, K., Sutton, C. J., McCray, G., Myers, H. L., & Lancaster, G. A. (2021). Determining sample size for progression criteria for pragmatic pilot RCTs: the hypothesis test strikes back!. *Pilot and feasibility studies*, *7*, 1-14. https://doi.org/10.1186/s40814-021-00770-x.

34. Jones, K,C., Weatherly, H., Birch, S., Castelli, A., Chalkley, M., Dargan, A., Forder, J.E., Gao, M., Hinde, S., Markham, S., Premji, S., Findlay, D., & Teo, H. (2024) *Unit Costs of Health and Social Care 2023 Manual.* Technical report. Personal Social Services Research Unit (University of Kent) & Centre for Health Economics (University of York), Kent, UK 10.22024/UniKent/01.02.105685. (doi:10.22024/UniKent/01.02.105685) (KAR id:105685)

16. APPENDICES

16.1 Appendix 1 – Safety Reporting Flow Chart



16.2 Appendix 2 – Stammering content for parents and carers of children who stammer

Stammering content for parents and carers of children who stammer			
Child age group	**Theme**	**Topic title and summary**	**Caregiver Activity description**
All	SuperPenguin Basics	**Welcome to SuperPenguin** This topic elaborates on how SuperPenguin is specifically designed for busy families, providing concise and targeted content that addresses both the needs of the child and the caregiver. By engaging with this topic, users will understand how SuperPenguin can seamlessly integrate into their daily lives, offering reliable support and encouraging the creation of a supportive network around children with a speech or language need. This foundational introduction sets the stage for caregivers to embark on an informative journey, ensuring they revisit lessons as needed and share the learning with others involved in caregiving. SuperPenguin aims to make a substantial difference in the quality of life for children with a speech or language need by fostering a supportive and knowledgeable community.	Reflective exercise: What are you hoping to achieve with SuperPenguin?
8-12	Foundations	**What is stammering?** Guided by speech-language therapist, this topic offers a clear introduction to stammering—a neurodevelopmental difference that affects speech. It explains how stammering can appear (sound repetitions, prolongations, silent blocks) and explores the physical and emotional strain it may cause. Key statistics show its prevalence in children and adults, noting that many youngsters outgrow it by age five while persistence depends on genetic, neurological, and environmental factors. By dispelling common myths and stressing that stammering is part of a child's unique communication style, not something to "fix", the topic equips parents with practical, supportive strategies championed by SuperPenguin.	Reflective exercise: Share the most memorable or helpful thing regarding stammering.
8-12	Foundations	**What can affect stammering** This topic explains how a child's stammer can vary in frequency and intensity from hour to hour or week to week, shaped by energy, emotions, social settings, and others' responses. Parents learn to create a relaxed, empathetic communication environment, use reflective activity to track their child's unique patterns, and adapt support as needs evolve. SuperPenguin equips families to nurture confident communication, whatever course the stammer takes.	Observation: identify what impacts or affects a child's stammering.

8-12	Foundations	**The stammering iceberg** This topic uses the “stammering iceberg” metaphor to show that the repetitions and blocks we notice are just the tip, while a much larger layer of emotional and psychological impacts lies unseen below the surface. By exploring this image, parents understand that real support must address both the observable and the hidden aspects of stammering. SuperPenguin supplies reflection tools and activities that guide caregivers toward empathetic, holistic strategies, strengthening a child’s communication and emotional well-being while easing stress around speaking.	Analyse and apply learnings: list ways to support child to make their environment more positive and encouraging (things that are already working and new approaches extracted from the learnings.
8-12	Foundations	**Language around stammering** This topic shows how the words we choose about stammering shape a child’s feelings and self-image. It urges parents to drop “good” or “bad” labels and instead use neutral, non-judgmental language that treats stammering as one natural way of speaking. Phrases such as “stammering more” or “stammering less,” woven into everyday conversation, foster a supportive tone and help children feel understood. The video also coaches parents to notice and validate the emotions that accompany stammering. By pairing respectful vocabulary with empathetic listening, families can reduce stigma, protect self-esteem, and nurture resilient communication.	Analyse and apply learnings: What are people in the child's inner circles approach to stammering? How can it be adjusted to be more supportive?
8-12	Foundations	**No limits** This topic covers why stammering should never limit a child’s ambitions. Using examples of well-known figures such as Ed Sheeran, Emily Blunt, Ed Balls, and Felicity Baker, it shows that people who stammer succeed across every field and that speech style does not define intelligence, talent, or capability. The content challenges headlines about “overcoming” a stammer, stressing that stammering is simply another way of speaking, not a flaw to be fixed. It encourages families to celebrate every voice, acknowledge the hard moments without letting them diminish self-worth, and look forward to a future where stammering is seen and accepted in everyday life. By reinforcing that “everything is possible,” the topic empowers children who stammer to pursue any goal with confidence.	Interview: our very own Ronan Miller (PhD), his journey as a person who stammers.
8-12	Stammering and Your Older Child	**Navigating changing awareness** This topic offers strategies and support as children develop greater awareness of their stammering during this transitional age. As children grow, they may become increasingly sensitive to external opinions and societal influences, which can affect their confidence and communication. The session offers insights into the developmental changes that children undergo and how these changes can affect their stammering. Parents are guided on how to maintain a supportive and empathetic environment, fostering open conversations about the child’s experiences and challenges. While this topic is tailored for parents dealing with stammering in their children, the strategies discussed can also be beneficial for other speech and language conditions, and applicable to broader roles and age groups. The content encourages parents to focus on the child’s message rather than the delivery, strengthening the child’s self-esteem and communication skills. This holistic approach ensures that regardless of the	Survey: A series of questions with Likert scale responses to assess the child's comfort in different speaking situations.

		condition, age, or role, users can adapt the guidance provided to suit their unique circumstances, making it versatile and widely applicable.	
8-12	Building Confidence and Resilience	**Supporting Emotions** This topic focuses on the importance of allowing children space to speak, even through hard stammers, to reinforce their ability to communicate and build self-confidence. Through calm and supportive interactions, parents can model problem-solving behaviours and engage in discussions about potential solutions to everyday challenges. The topic emphasises creating an open and non-judgmental environment where children can express their feelings freely, which is crucial in helping them manage emotions related to stammering. By incorporating activities that encourage brainstorming and evaluating solutions, this module provides a structured approach to overcoming communication barriers. While designed with parents of children who stammer in mind, the strategies presented can be applied to various conditions and age groups, offering support to any family seeking to enhance their communication dynamics. This comprehensive approach not only benefits children but also equips parents with the tools to foster a nurturing and understanding atmosphere, promoting overall family resilience.	Interactive scenario activity: A series of school-related scenarios and responses to choose from that best support the child's emotions.
8-12	Building Confidence and Resilience	**Building Confidence** The aim is to boost children's self-esteem and communication skills by fostering a supportive and understanding environment. Through carefully structured activities, parents learn to model calm behaviour, brainstorm solutions, and explore the pros and cons of different approaches. This topic encourages collaboration, guiding children to take the lead in identifying and solving everyday challenges, thereby enhancing their resilience. By practising problem-solving skills, children can navigate speaking situations with greater confidence. The topic underscores the importance of acknowledging and validating children's feelings, allowing them to express their anxieties openly. Furthermore, it promotes the development of a safe space where anxieties can be managed without judgment. The strategies outlined in this topic are adaptable, making it a valuable resource not only for parents dealing with stammering but also for those supporting children with various needs. By focusing on the strengths and capabilities of each child, this session aims to empower users to foster a nurturing and empowering environment, regardless of the condition, role, or age group they are supporting.	Guide: Step by step for carers to guide the child in solving problems.
8-12	Supportive Space at School	**Changing to Secondary School** This topic provides strategies for a smooth transition to secondary school. It focuses on creating a supportive educational environment that fosters confidence and personal growth. The aim is to help children feel comfortable in new settings, develop social connections, and gain speaking confidence through structured approaches. The content addresses typical challenges during this transition, such as larger school environments and evolving social	Interactive scenario activity: A series of scenarios of challenges a child may face when transitioning to secondary school are presented, along with a multiple choice of strategies for each challenge to choose from.

		dynamics, and offers practical solutions like understanding different 'zones' of comfort, stretch, and panic to help children manage their anxieties. While primarily intended for parents of children with stammering, the strategies outlined can also be beneficial for other roles, such as educators and family members, and for children with different conditions or within varying age groups. By promoting empathy, understanding, and collaboration among parents, schools, and children, this topic aims to create a positive experience in navigating new educational landscapes, ensuring every child can thrive regardless of their specific challenges.	
8-12	Supportive Space at School	**Dealing with Bullying** This topic offers essential strategies to manage and overcome the challenges of bullying related to stammering. It emphasises the importance of creating a supportive environment both at school and home. The aim is to equip parents with tools to recognise early signs of bullying and to encourage open communication, thereby helping their child to build resilience and confidence. Through interactive components, parents will learn how to communicate effectively with school staff, explore coping strategies, and boost their child's self-esteem. While the primary focus is on stammering, the methods and strategies presented can be beneficial for a wider audience, including different age groups and conditions, promoting inclusivity and empathy. This topic not only focuses on the emotional well-being of the child but also provides the parent with reflective activities to understand their role better and grow with their child. It encapsulates the fundamentals of fostering a positive mindset and encourages collaboration among teachers, students, and parents to create a safe and inclusive space for all children.	Journal activity: The journal activity covers several prompts: signs to recognise bullying, copying strategies, communication plan with the school, ways to build child's confidence and reflecting on one's own feelings.
8-12	Supportive Space at School	**Creating a Stammer-Safe Classroom:** **A Guide for Teachers** This topic aims to support educators with strategies to foster a supportive and inclusive classroom environment for children who stammer. Recognising the unique challenges faced by children aged 7-12, this session provides insights into the psychological and social dynamics of stammering. The key strategy involves promoting flexible communication methods and encouraging open conversations to reduce the stigma associated with stammering. While the primary focus is on parents of children who stammer, the approaches discussed are applicable to other conditions and roles, making this content beneficial for a broader audience. By understanding the needs and feelings of children who stammer, educators can create a classroom culture that respects diverse communication styles and empowers children to participate without fear of judgment. This not only enhances the learning experience for children who stammer but also fosters empathy and respect among all students. Ultimately, this topic seeks to build a community of support that enables all children to thrive in their educational journey.	Discussion: Parents are encouraged to have an open dialogue with their child using thoughtful questions to better understand their child's unique needs and preferences. This fosters a supportive environment for confident communication.

2-12	Toolkit (extra resources)	**Stammering myths** Addresses common myths about stammering, providing accurate facts to debunk misconceptions. It highlights the neurological basis of stammering, corrects false assumptions about personality, intelligence, and psychological causes, and emphasises supportive communication strategies.
2-12	Toolkit (extra resources)	**What you focus on grows** This resource covers the importance of focusing on the whole child rather than their stammering. It explores how overemphasising fluency can overshadow the child's true message, affect their self-image, and shift the focus away from meaningful connection. By modeling acceptance and supporting confident communication, carers can foster resilience and self-belief in their children. Real-life examples and testimonials illustrate how small shifts in focus can make a significant impact.
2-12	Toolkit (extra resources)	**Bilingualism** This topic explores bilingualism in children, highlighting that it is a strength, not a cause of stammering. It explains that children can naturally learn two languages, and that stammering will appear in both languages if present. Code-switching is described as a normal and healthy part of bilingual development. Parents are encouraged to speak their home language regularly, as this strengthens cultural connections, builds a strong foundation for learning additional languages like English, and supports overall communication skills. Maintaining bilingualism is a lifelong gift that benefits both identity and learning.
2-12	Toolkit (extra resources)	**Minding less about stammering** This topic covers mindful, supportive approaches for parents of children who stammer, using inspirational quotes and practical tips to foster confidence, emotional connection, and self-worth. It emphasizes presence over correction, valuing the child's communication efforts over fluency, and encouraging trust and calm support in everyday interactions.
2-12	Toolkit (extra resources)	**Life through a child's eyes** This resource covers understanding stammering from a child's perspective and shifting the caregiver's approach from trying to "fix" speech to offering supportive, empathetic presence. It addresses common parental fears, highlights the impact of well-meaning corrections, and encourages fostering confidence over fluency through acceptance and connection.
2-12	Toolkit (extra resources)	**Managing thoughts** This topic covers strategies to help children manage their thoughts around stammering by identifying helpful versus unhelpful thinking. It introduces simple, supportive techniques—such as self-kindness, growth mindset, mindful breathing, and positive reframing—to build emotional resilience and confidence in their speaking journey.

16.3 Appendix 3 - Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
01	2.0	22-Oct-2025	Andrew Skeggs	1. Minor wording changes to clarify Informed Consent will be self-completed by the participant online for the main feasibility study and will provide 'consent to contact' for their email/mobile number to be used for this purpose. 2. Clarification of the identification of AE's process at each study timepoint 3. Removal of the 'Journal' function on the SPMA 4. Minor typographical changes
02	3.0	20-Nov-2025	Andrew Skeggs	1. Clarification in section 7.8 (Trial Assessment) that the SFBT will be completed by the participant after randomisation 2. References to the Caregiver workshop have been removed from the treatment adherence definition in section 11.3.2 and safety population in section 11.4 as this will not be used in the analysis as an indicator of adherence and is not standard practice across all sites 3. The option of offering a carer workshop to participants has been added to section 7.1 4. Minor typographical changes
03	4.0	19-Jun-2026	Andrew Skeggs	Section 7.10 (Qualitative Assessments – Nested Studies) updated to state that Caregivers (for themselves and/or on behalf of their child) and SLT's will be given a £20 voucher as a thank you gesture and for recompensating their time for participating in the qualitative study interviews.