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

Submission date	<b>Recruitment status</b> Recruiting	[X] Prospectively registered		
24/07/2025		☐ Protocol		
Registration date	Overall study status Ongoing  Condition category Mental and Behavioural Disorders	Statistical analysis plan		
05/08/2025		Results		
Last Edited		Individual participant data		
11/09/2025		[X] Record updated in last year		

### Plain English summary of protocol

Background and study aims

This study is exploring a new mobile app called Super Penguin, designed to support families of children who stammer. The app was co-created with parents and speech and language therapists and is meant to be used alongside regular NHS speech and language therapy. It offers personalised exercises and resources to help parents feel more confident in supporting their child's communication and aims to reduce stress and anxiety. The study will help researchers decide whether to run a larger trial in the future and how best to do that across the UK.

## Who can participate?

Parents or main caregivers of children aged 8 to 12 years who have been referred for NHS speech and language therapy for stammering and are assessed as needing therapy.

#### What does the study involve?

Participants will be asked to complete online questionnaires at four different times: before therapy starts, when therapy begins, about four months later, and again five months after that. The study fits around normal NHS therapy appointments and lasts up to 11 months from the time of consent.

What are the possible benefits and risks of participating?

The app may help parents feel more confident and less stressed when supporting their child's communication. There are minimal risks, though some users might find the app frustrating or difficult to use. Support will be available to help with any issues.

Where is the study run from? Benetalk Ltd (UK)

When is the study starting and how long is it expected to run for? July 2025 to July 2027

Who is funding the study? National Institute for Health and Care Research (NIHR) (UK) Who is the main contact?

Dr Ronan Miller, ronan@benetalk.com

# Contact information

## Type(s)

Public, Scientific, Principal investigator

#### Contact name

Dr Ronan Miller

#### Contact details

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# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

**Integrated Research Application System (IRAS)** 

333572

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 58389, NIHR206439

# Study information

#### Scientific 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

#### Acronym

**SUPPORT** 

#### **Study objectives**

Primary objective:

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).

#### Secondary objectives:

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

#### Ethics approval required

Ethics approval required

#### Ethics approval(s)

approved 21/08/2025, London - Brent Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048131; brent.rec@hra.nhs.uk), ref: 25/PR/0918

#### Study design

Interventional randomized controlled trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

# Health condition(s) or problem(s) studied

Stammer

#### **Interventions**

This project is a multi-centre, two-arm, mixed-methods, open-label randomised controlled feasibility study. We will recruit 34 parents or main caregivers of 8- to 12-year-old children who have been referred to NHS speech-and-language therapy (SLT) for stammering. After giving consent, each caregiver is randomly allocated—by computer, in a 1:1 ratio—to either (a) a control group that follows standard NHS SLT only or (b) an intervention group that follows the same NHS SLT plus receives free access to the SuperPenguin mobile app, which provides practical activities and guidance for supporting their child at home. Because families will know whether they are using the app, there is no blinding.

Participation in the study will be for a maximum of 11 months and fits entirely around normal SLT appointments; no extra clinic visits are added. Caregivers complete the same online questionnaires at four points: (1) up to two months before therapy begins (baseline and randomisation), (2) on the day therapy starts, (3) roughly four months later—or sooner if therapy finishes early—and (4) five months after that. The questionnaires cover parental confidence (PPRS), therapy goals (SFBT), quality of life (EQ-5D-3L) and service-use costs; the child's SLT also records a routine rating (TOMs) at points 2-4. Intervention-group parents complete one additional usability survey (MAUQ) about the app. Alongside these quantitative measures, an embedded qualitative study will invite up to 10 caregivers, 10 children and 10 SLTs to take part in voluntary Microsoft Teams interviews (30–45 minutes) to explore the app's usability, acceptability and the practicality of the study procedures; some participants may have a follow-up chat later.

#### Intervention Type

Behavioural

## Primary outcome(s)

Feasibility outcomes:

- 1. Eligibility rate is measured using screening logs at baseline
- 2. Approach rate is measured using site recruitment logs at baseline
- 3. Consent rate is measured using consent forms at baseline
- 4. Randomisation rate is measured using trial database records at baseline
- 5. Completion rate of outcome measures is measured using questionnaire return logs at baseline, therapy start, 4 months post-therapy start, and 9 months post-therapy start
- 6. Participation rate is measured using trial database records at baseline and throughout the study duration
- 7. App usage is measured using SuperPenguin app analytics (time spent and modules completed) throughout the study duration
- 8. Treatment allocation adherence is measured using trial database records throughout the study duration
- 9. Reasons for non-randomisation and dropouts are measured using site logs and participant feedback throughout the study duration

#### Key secondary outcome(s))

- 1. Caregiver confidence is measured using the Palin Parent Rating Scales (PPRS) at baseline, therapy start, 4 months post-therapy start, and 9 months post-therapy start
- 2. Therapy goals are measured using the Solution Focused Brief Therapy (SFBT) questionnaire at baseline, therapy start, 4 months post-therapy start, and 9 months post-therapy start
- 3. Quality of life is measured using the EQ-5D-3L questionnaire at baseline, therapy start, 4 months post-therapy start, and 9 months post-therapy start
- 4. Service-use costs are measured using the Resource Use Questionnaire at therapy start, 4 months post-therapy start, and 9 months post-therapy start
- 5. Therapy outcomes are measured using the Dysfluency Therapy Outcome Measures (TOMs) at therapy start, 4 months post-therapy start, and 9 months post-therapy start
- 6. App usability is measured using the mHealth App Usability Questionnaire (MAUQ) at 4 months post-therapy start
- 7. App usability and acceptability are measured using semi-structured interviews with caregivers and SLTs at around 9 months
- 8. Child confidence and communication experiences are measured using semi-structured interviews with children at around 9 months
- 9. Economic viability is measured using the EQ-5D-3L and Resource Use Questionnaire at therapy start, 4 months post-therapy start, and 9 months post-therapy start
- 10. Safety is measured using adverse event logs and device-related event reports throughout the study duration

# Completion date

30/06/2027

# **Eligibility**

# Key inclusion criteria

Main feasibility study:

1. Caregivers must be 18 years or over

2. Their child has been referred for speech and language therapy for stammering and has been assessed as requiring access to speech and language therapy in line with usual practice. Their child is 8-12 years old.

#### Qualitative interviews:

- 1. Caregivers are taking part in the feasibility study and have been randomised to access the app. Are able to conduct online interviews in English.
- 2. Speech and language therapists who have randomised participants to access the app and can complete an online interview in English.
- 3. Children aged 8-12 years whose caregiver has been randomised to access the app. Are able to conduct an adult-led speaking activity in English. Has been referred for speech and language therapy support for stammering.

#### Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

#### Age group

Mixed

#### Lower age limit

8 years

#### Sex

All

## Key exclusion criteria

Main feasibility study:

- 1. Caregivers are unable to provide informed consent. Are unable or unwilling to complete study assessments in English.
- 2. Families with more than one child who stammers, 8-12 years old, and both have been referred for therapy.

#### Qualitative interviews:

- 1. Caregivers are unable to give informed consent.
- 2. Speech and language therapists who are unable to give informed consent.
- 3. Children whose caregiver has not provided informed consent for their participation in the interviews.

#### Date of first enrolment

01/12/2025

#### Date of final enrolment

30/06/2026

# Locations

#### Countries of recruitment

#### **United Kingdom**

# England

# Study participating centre South West Yorkshire Partnership NHS Foundation Trust

Trust Headquarters Fieldhead Hospital Ouchthorpe Lane Wakefield United Kingdom WF1 3SP

# Study participating centre Kent Community Health NHS Foundation Trust

Trinity House 110-120 Eureka Park Eureka Business Park Ashford United Kingdom TN25 4AZ

# Study participating centre Kingston Hospital NHS Foundation Trust Galsworthy Road

Kingston upon Thames United Kingdom KT2 7QB

# Sponsor information

# Organisation

Benetalk Ltd

# Funder(s)

# Funder type

Government

#### Funder Name

NIHR Central Commissioning Facility (CCF)

# **Results and Publications**

#### Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are stored in non-public repositories and are available from the Sponsor upon reasonable request.

#### Contact for Access:

Requests should be directed to the study Sponsor, BeneTalk Ltd., via email to speak@superpenguin.com.

#### Repository / Storage Location:

The quantitative dataset is securely held in a validated electronic data capture system managed by the Derby Clinical Trials Support Unit (DCTSU).

The qualitative dataset (anonymised transcripts) is archived in the non-public Leeds Beckett University (LBU) Research Data Repository.

The integrated, final dataset will be held by the Sponsor (BeneTalk Ltd).

#### Type of Data Available:

Anonymised Individual Participant Data (IPD) will be shared. This includes the full quantitative dataset (demographics, PPRS, SFBT, TOMs, MAUQ, EQ5D-3L, Resource Use Questionnaires) and the fully anonymised qualitative interview transcripts.

## Availability Timeline:

Data will be available for request 12 months after the publication of the study's main findings and will remain available for a period of 5 years.

#### Access Criteria:

Data will be shared with bona fide researchers at academic or non-commercial institutions for the purpose of ethically approved, non-commercial secondary research. A legally binding Data Sharing Agreement (DSA) must be executed before any data is transferred.

#### Access Mechanism:

Researchers must submit a formal written proposal outlining their research plan and ethical approval. Requests will be reviewed by a Data Access Committee, with final approval from the Joint Controllers (BeneTalk Ltd and Leeds Beckett University).

## Consent and Anonymisation:

Consent for sharing anonymised data for future research was obtained from all participants. The dataset will be fully anonymised by removing all direct identifiers (e.g., names, NHS number, contact details) and key indirect identifiers to minimise the risk of re-identification.

#### Ethical or Legal Restrictions:

The use of the data is strictly governed by the terms of the Data Sharing Agreement, which prohibits any attempt to re-identify participants. All data sharing will comply with UK GDPR and the Data Protection Act 2018.

#### IPD sharing plan summary

# Stored in non-publicly available repository, Available on request

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	SuperPenguin WP7 version 2.0	23/07/2025	04/09/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes