

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

PARTICIPANT INFORMATION SHEET

Local researcher (PI)

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Introduction

- We are conducting a study assessing the introduction of a **mobile app called "SuperPenguin"** intended to support families alongside usual care pathways for **children who stammer (CWS)**.
- As a family referred to us for support, you may be eligible to take part in this study, if you wish to do so.
- **Your access to usual care will not change**, but if you agree to take part, you may be selected to access the Super Penguin app.
- This choice will be random; neither the research team, your NHS care team or you can decide whether you will access the app or not.
- During the study, **we will ask you to complete questionnaires**, so the researchers can evaluate how the app affects the people who access it.
- If you decide to take part, you will be involved in the study for a **maximum of 11 months**, starting from the time when you complete the first questionnaires.
- The researchers will use information from this study to decide whether to do a larger study and to decide how best to run that study across the UK.

Throughout this information sheet we will refer to "your child". This refers to the child referred to speech and language therapy, who you have been identified as having caregiving responsibilities for.

Keywords/ abbreviations:

CWS: Children who stammer

SLTs: Speech and Language Therapists

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What's involved?

What is the SuperPenguin app?

- We have developed the "SuperPenguin" mobile app with caregivers of children who stammer (CWS) and speech and language therapists (SLTs).
- It is designed to **work alongside speech and language therapy (SLT)** delivered in the NHS.
- The app aims to **provide information about stammering** and help create a supportive communication environment for children who stammer.
- It has **exercises and resources** that can be personalised to families.
- It aims to help caregivers by **increasing their confidence** in supporting a child's communication, while reducing anxiety and stress.
- The SuperPenguin app is a UKCA marked Class I medical device being used within its intended purpose.

Why do we need to do a research study?

- Before the wider NHS starts using this app, we need to provide evidence that it does what it aims to do.
- This research study will assess if we can introduce the SuperPenguin app and run a larger study in the future to get the information we need to support wider roll out in the NHS.
- We are inviting **34 families** referred to speech and language therapy at different NHS sites to take part in the study.
- Half of the families will access the SuperPenguin app in addition to usual NHS care, and the other half will access usual NHS care only.

Do I have to take part?

- **No, you do not have to take part.** If you decide not to, then we may ask your reasons why, as this will help us in designing a future research study, but you do not have to provide a reason.
- You will continue accessing speech and language therapy for your child as usual.

What would taking part involve?

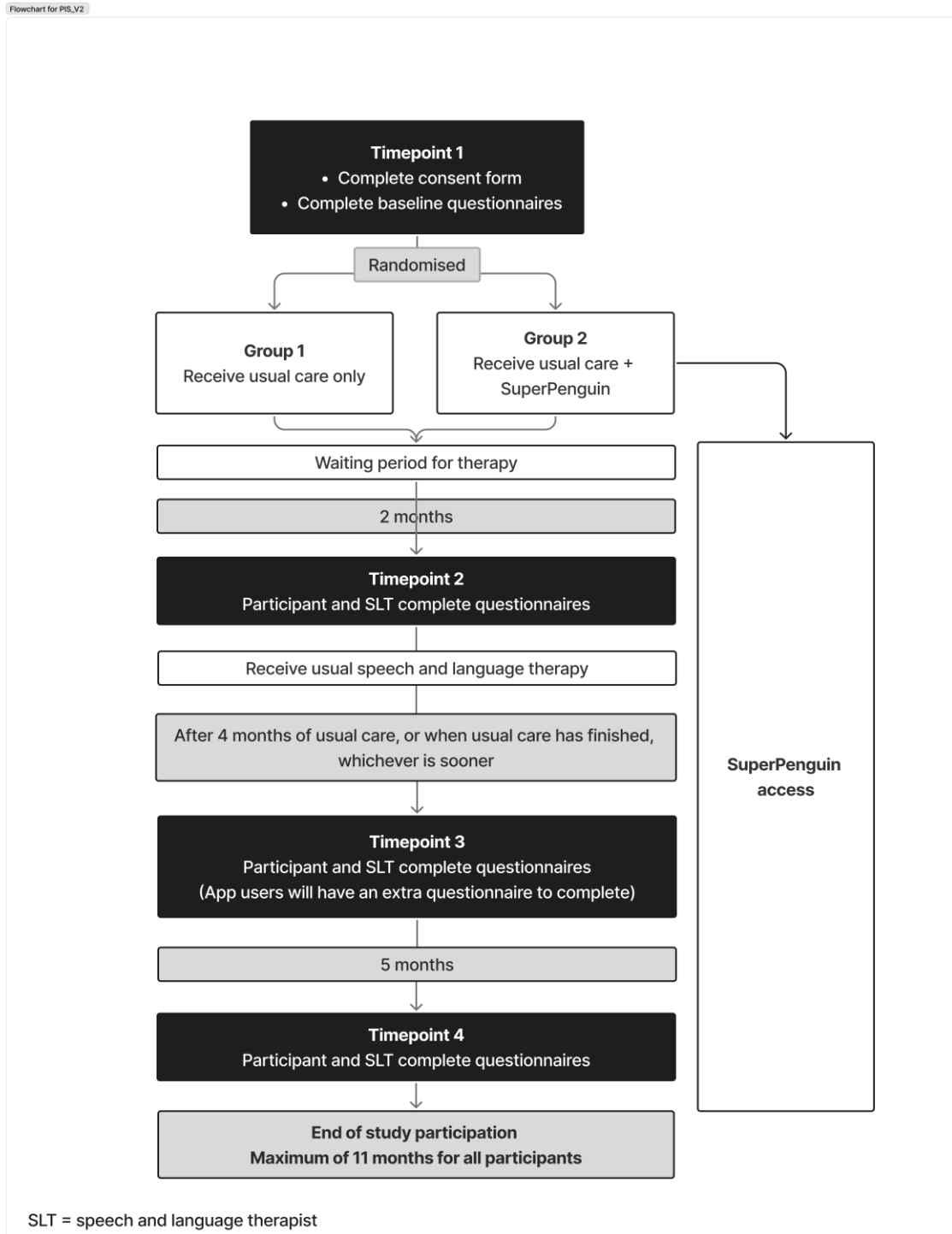
- Taking part will involve you completing questionnaires alongside the usual NHS care pathway.
- If we give you access to the SuperPenguin app, you will be able to use it **before, during and after** you and your child accesses therapy for stammering.
- You will also complete questionnaires at 4 timepoints **before, during and after** you and your child access therapy for stammering.

- 1) **Timepoint 1** - You will sign a consent form and provide some information to the study team (who may also be your SLT team) about you and your child (age, gender, ethnicity, postcode, and your highest level of education). We will ask you to complete questionnaires which serve as the starting point or "baseline" for the study.
- 2) **Randomisation** - You will be randomly assigned to use the app in addition to usual therapy, or receive therapy alone, which is usual practice. There is more information about randomisation on page 6.
- 3) **Timepoint 2** - Just before you are due to start therapy, we will ask you to complete some more questionnaires.
- 4) **Timepoint 3** - Either 4 months after you start therapy, or once you have finished therapy (whichever is sooner), we will ask you to complete the same questionnaires again. If you have been accessing the app, there will be one extra questionnaire for you to complete.
- 5) **Timepoint 4** - After another 5 months, we will ask you to complete the same questionnaires again.
- 6) **After this, your participation in the study will end.** If you agree, we will send you updates on the study to let you know the results and what we plan to do next.

About the questionnaires:

- The questionnaires will be completed electronically and will take you short while of your time to complete.
- The questionnaires are designed to measure how you are feeling and your goals for speech and language therapy.
- The speech and language therapist you see will also complete a questionnaire about your child's therapy.
- Families using the app will complete an additional questionnaire (at timepoint 3) about the usability of the app.

Flowchart of the study schedule:



About the randomisation:

- Sometimes we need to make comparisons because we do not know which way of helping people is best (we do not know if the SuperPenguin app works or not)

- To make this comparison as fair as possible, people need to be put into groups and then compared.
- The groups are selected by a computer to make sure they are chosen by chance.
- Each group then receives different help and these are compared.
- In this study, you are just as likely to be given the app to use in addition to standard care as you are likely to just receive standard care.
- If you like, you can watch the video linked below in the QR code that explains how randomisation works



Accessing the SuperPenguin app:

- If we give you access to the SuperPenguin app, we will provide you with a link to download the app for your device.
- If you do not have access to a smartphone or device to access the app, we will provide one for you to use during the study.
- We will ask you to provide your email address and phone number to create an account. **More information about how we use your data is further on in this information sheet.**
- There are no minimum requirements to use the app, you can use it as little or as much as suits you.
- Your access to the SuperPenguin app will no longer be available once you have finished your last study timepoint.

Interviewing users of the app

- Part of this study includes researchers from Leeds Beckett University speaking to participants to find out more about their experience of using the app.
- If you and your child choose, your child can also take part in an interview.
- You will only be asked about this if you are selected to use the app.
- When you are given information about the app you will be given a separate information sheet about the interviews
- All interviews are optional - you can take part in this, or choose not to, and it will not impact your involvement in the main study, access to the app or your usual NHS care.

What are the possible benefits of taking part?

- We cannot say that you will benefit directly from taking part in the study, as you may not be given access to the app (and we do not yet know if the app does what it aims to do).
- Research delivers wider benefits to society and this study might contribute to how care is provided to children who stammer in the future.

What are the possible disadvantages and risks of taking part?

- Taking part in this study will require your time to complete questionnaires.
- Some of these may be routine for your child's therapy, but this can vary.
- We have tried to make completing the questionnaires as easy as possible, and if you have any trouble completing them, we encourage you to reach out to us.
- Accessing the app itself does not come with any added risks, except for potential frustration if you find the app difficult to use.

I would like to take part. What do I need to do next?

- Take the time to read this information sheet and the consent form provided and ask any questions you may have.
- Discuss the study with family and friends if you wish.
- Members of the research team will be in touch to discuss the study further and answer any questions you may have.
- They will ask you to sign a consent form to confirm your agreement to take part and give you a copy of this form to keep.
- Keep this information sheet for further reference.
- You may find it helpful to make notes of any questions in the space below.

Notes:

Further information

When is the study expected to end?

- Your involvement in the study will end once you have completed Timepoint 4, or before if you choose to stop participating which will be up to 11 months.
- We are expecting the study to end once all 34 families have completed Timepoint 4. is anticipated to be in mid to late 2027

• **What if something goes wrong?**

- If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [site contact details].
- If you remain unhappy and wish to complain formally, you can do this by contacting [insert local PALS details].
- If you are harmed because the study was designed or managed negligently, you may be able to claim compensation from BeneTalk Ltd. Neither the NHS nor BeneTalk Ltd operates a formal “no-fault” compensation scheme.

Can I change my mind about taking part?

- Yes. At any time, you can decide you no longer wish to take part, and it will not affect the care you and your child receive.
- Contact the research team using the details in this information sheet who will be able to record your decision and talk through your options.
- Understanding why you may no longer wish to take part is helpful when planning research studies, but you do not have to tell us.
- It is ok if you still want to receive updates about the study after you have decided to stop taking part.
- If you withdraw from the study, we will keep and continue to use all your previously collected data. We will, however not collect any further data about you.

What will happen to the results of this study?

- We will use the results of study to move forward to a bigger study with more families involved.

- What we learn from this study will help us to conduct a study that families want to take part in, and can help us best gather information about the SuperPenguin app.
- Once we have completed the study, we will report our findings to the NIHR, who funded the study, and make our findings publicly available by reporting them to an international journal and sharing them at academic conferences. We will also share findings with stammer charities and other interested parties.
- If you would like to receive information on the results of the study, you can indicate this on the consent form and we will keep you updated.
- It will not be possible to identify you in any of the information or results we share.

Who is organising and funding this study?

- The National Institute for Health and Care Research (NIHR) has awarded Benetalk Ltd money to fund this study.
- The developers of the SuperPenguin app (Benetalk Ltd) are responsible for the overall conduct of the study and are known as the "Sponsor".
- Derby Clinical Trials Support Unit is managing the day to day running of the study.

Commercial development

- Findings from this study could contribute to the future commercial development of the product being tested. If any commercialisation does occur, you will not receive any financial return or share of profits.

How have patients and the public been involved in this study?

- We have been working with caregivers of CWS, young adults who stammer, and speech and language therapists to develop the app.
- They have also helped us develop this study and have provided feedback on this documentation.

Who has reviewed this study?

- All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests.
- The <XXX> REC has reviewed and approved this study.
- The Health Research Authority (HRA) has also reviewed and approved this study.

Will you tell my GP about the study?

- With your permission, we will tell your GP that you have agreed to take part in the study.
- We will tell them if you have been given access to the SuperPenguin app or not.

What if relevant new information becomes available?

- If we get new information about the app that is relevant to your participation in the study, we will tell you and to discuss this with you.
- It may be appropriate for you to decide if taking part is still right for you. If this is the case, we will ask you to sign a consent form to confirm you are happy to continue.
- If the study is stopped for any other reason, we will tell you and your standard care will continue as usual.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your:

- Age and the age of your child
- Gender
- Ethnicity
- Contact details: email address and telephone number
- Postcode
- Highest level of education
- If your child has any need in addition to having a stammer (you **do not** have to tell us what this need is if you do not want to)

People will use this information to do the research and to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Benetalk Ltd (SuperPenguin) is the sponsor of this research.

Benetalk Ltd is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- NHS organisations (Derby Clinical Trials Support Unit, part of University Hospitals of Derby & Burton NHS Foundation Trust)

We will keep all information about you safe and secure by:

- Storing any personal or identifiable information about you (e.g., contact, name, postcode) on a secure password-protected folder away from the research data.
- Using data storage systems recommended as secure by NHS organisations and universities that are routinely backed-up and are GDPR compliant.

International transfers

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 5 years after the study ends. The study data will be fully anonymised and securely archived and then destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this
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Where can you find out more about how your information is used?

You can find out more about how we use your information:

- our leaflet www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to the Sponsor's Data Protection Officer, Orla Purdon [orla@superpenguin.com]

Contact Details

<Local contact details, including PALS here:>



Thank you for taking the time to read this information sheet.