Pre and post-operative voice therapy (PaPOV) for benign vocal fold lesions: Non-randomised, multicentre feasibility trial with nested process evaluation

IRAS Reference: 295725

Participant Information Sheet; Version v2.0, Dated 1-Dec-2022

Principal Investigator: Vicky Booth

Contact details

Investigator 1

Name: Vicky Booth

Contact: 0115 8230237
Email: Vicky.booth@nuh.nhs.uk

Investigator 2

Name: Anna White

Contact: 07812 278238
Email: Anna.white24@nhs.net

1. What is the purpose of the study?

One in three people will experience a voice problem in their lifetime and there are many different causes of this. Some people develop benign lumps or bumps on their vocal folds and these can prevent the vocal folds from closing fully or vibrating normally. This can lead to hoarseness, voice loss and sometimes pain or strain in the throat. Vocal fold polyps, cysts and papilloma are examples of these lumps and bumps, which collectively are called 'benign vocal fold lesions'.

Treatment for benign vocal fold lesions varies. Evidence suggests that patients may benefit from voice therapy before and after their operation, but there is currently no accepted standard of care. We have undertaken research with patients and clinicians to develop a package of voice therapy for patients having surgery on their vocal folds. This programme includes advice, information and exercises for patients to do before and after their surgery.

We now need to see whether this voice therapy programme is acceptable to patients and clinicians. We need to understand whether it is feasible to run a study where patients who are having surgery, also receive this voice therapy programme. This study will consider whether patients are happy to take part in this study, whether they complete the voice therapy , and what they think about the exercises and information given.. We will use these findings to decide whether a larger trial would be useful in the future to evaluate the effectiveness of this voice therapy.

2. Who has reviewed this study?

Research in the NHS is usually looked at by an independent group called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a

favourable opinion by the London – West London & GTAC Research Ethics Committee: REC reference 22/LO/0859.

The study has also been reviewed and approved by the Health Research Authority and the Research & Innovation department of Nottingham University Hospitals NHS Trust. The Nottingham University Hospitals NHS Trust will act as the 'Sponsor' (i.e., the lead NHS hospital) for this research. The National Institute for Health and Care Research (NIHR) will fund this research. This research is being undertaken as part of a PhD qualification.

3. Why have I been asked to take part?

a) Why have I been asked to take part?

You are being invited to take part because you have been diagnosed with a benign vocal fold lesion on your vocal fold and have been offered surgery to help treat this. We are inviting 40 participants like you to take part from two hospitals

b) Do I have to take part in this study?

No. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. If you decide to take part you are free to leave the study at any time and without giving a reason.

A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive.

4. What do I have to do?

This section describes the different appointments that you will have if you take part. There is also a flow chart to summarise this on page 6.

After you have consented, you will have an initial assessment with the Research team by phone on a video call or face to face. This may be at the same time as the research team talk you through the consent process or can be at another appointment if you would prefer. You will be asked questions about your voice and complete some questionnaires. The questionnaires ask about your voice, your quality of life overall and any expenses or costs that you have had because of your voice problem. We will also help you make a recording of your voice whilst you produce some sounds and read a passage of text aloud. For face to face appointments this recording will be done using an app on an NHS smartphone. For video call appointments, this recording will be done by downloading a freely available app to your smartphone or tablet. This appointment will take 30-45 minutes.

After this initial assessment your local Speech and Language Therapist will contact you to arrange your pre-operative voice therapy sessions. You will have one or two sessions of voice therapy before your operation. Voice therapy sessions will either be done face to face at the hospital or via a video link. In these pre-operative voice therapy appointments you will be given information and advice about your voice, your diagnosis and your surgery. You will develop goals for your voice and you will be taught voice exercises to help produce your voice in a healthy way. These appointments usually last between 30-45 minutes. Some of these sessions may be video recorded so that we can check whether all parts of the voice therapy programme are being delivered. The recording of sessions is optional and you do not have to agree to this. Any recordings made will be stored on a secure NHS network and viewed only by the research team. Once the videos have been analysed, the recording will be deleted.

After your pre-operative voice therapy, you will come into the hospital for surgery to remove the lesion from your vocal fold. The timing of this will depend on waiting lists for surgery. All details about the surgery and your time in hospital will be given to you by the clinical team at your hospital. You will receive a follow up appointment with your doctor to look at your vocal folds and discuss the outcome of the surgery 6-12 weeks after your surgery. The research team are not involved in the surgery or your follow up with the Doctor.

After your surgery your local Speech and Language Therapist will contact you to arrange your post-operative voice therapy sessions. The number of sessions will vary depending on how you are recovering but is likely to be between one and four sessions. These sessions will be done either face to face or via video link and will vary in length depending on how you are getting on and the level of support you need. The aim is to support you in your recovery after your operation and to help improve the sound, strength

and stamina of your voice. After your final voice therapy session, you will be asked to complete a short questionnaire asking how closely you followed the advice and exercises given by your therapist.

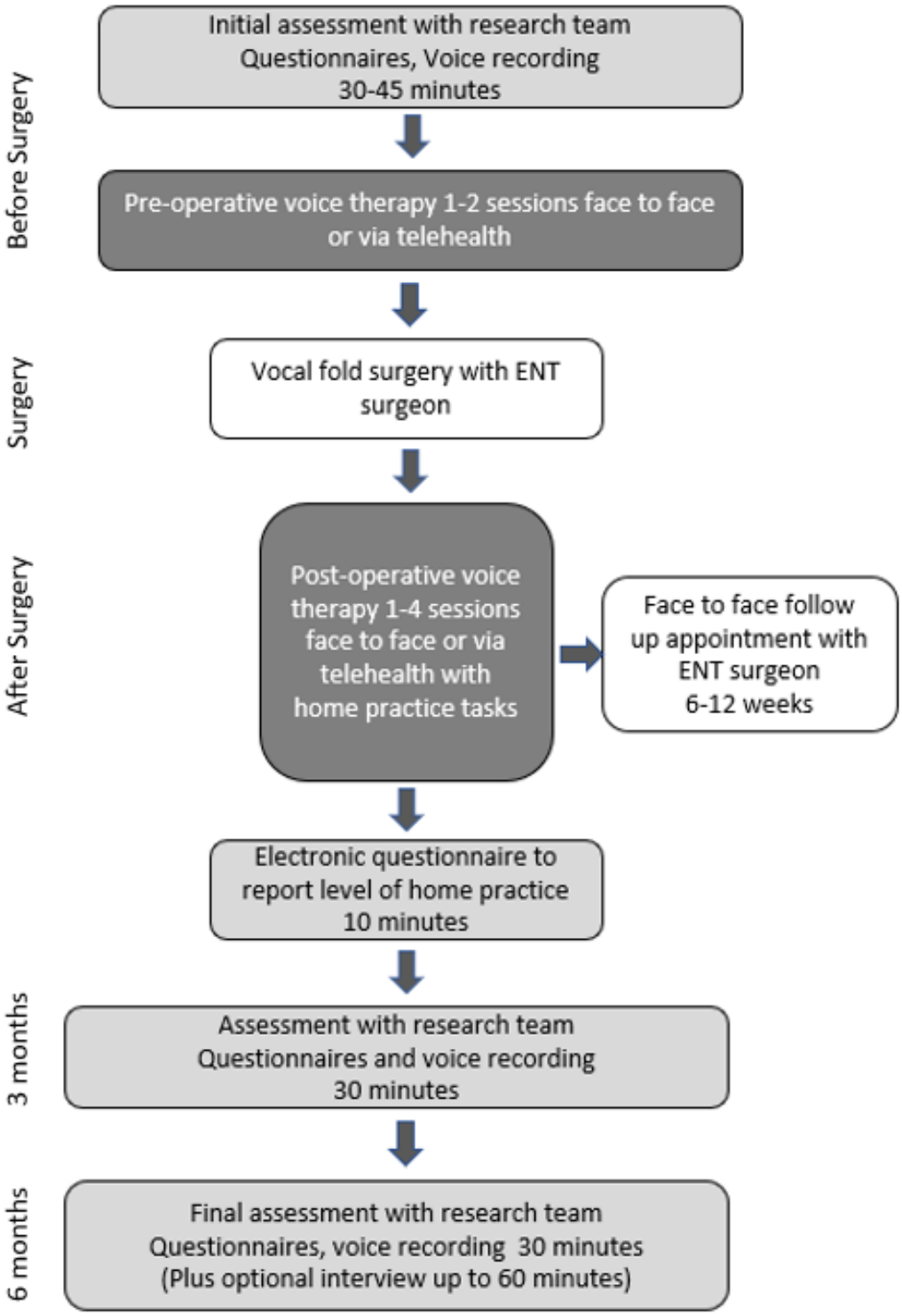
Two extra appointments will be made for you with the research team three and six months after your surgery to repeat the questionnaires and voice recordings that you did in your first appointment. This can be done by phone, video link or face to face, depending on your choice and will last approximately 20-30 minutes.

Finally, we will be inviting anyone who has been involved in the study to be interviewed to talk about their experiences of the study and the voice therapy they received. The interview will be done over the phone or video link and will take between 20 to 60 minutes depending on how much you have to say. The interview will be audio recorded and written out word for word by a professional transcription service with whom Nottingham University Hospitals NHS Trust has a contractual agreement in place to protect confidentiality. Pseudonymised transcripts will be analysed at the University of Nottingham. Upon completion of analysis, data will be deleted from University of Nottingham systems. You can decide at a later stage if you wish to take part in this interview or not.

You will not be paid to attend voice therapy appointments or ENT appointments. We will complete questionnaires and gather voice recordings electronically or over the phone where possible to avoid additional trips to the hospital. A small inconvenience payment will be offered to you for completing the additional research questionnaires and voice recordings (£10 per research clinic). An inconvenience payment of £15 will also be offered to any participant who undertakes the final interview.

If you do decide to take part in the study, you must report any problems you have to your study nurse or doctor. There is more information on this in section 6. There is also a contact number given at the end of this information sheet for you to phone if you become worried at any time. In the unlikely event of an emergency occurring during the conduct of the study, we may contact your nominated next of kin.

The flow chart on the following page summarises your involvement if you chose to take part.


Before Surgery
Initial assessment with research team
Questionnaires, Voice recording
30-45 minutes
Pre-operative voice therapy 1-2 sessions face to face or via telehealth
Surgery
Vocal fold surgery with ENT surgeon
After Surgery
Post-operative voice therapy 1-4 sessions face to face or via telehealth with home practice tasks
Face to face follow up appointment with ENT surgeon
6-12 weeks
Electronic questionnaire to report level of home practice
10 minutes
3 months
Assessment with research team
Questionnaires and voice recording
30 minutes
6 months
Final assessment with research team
Questionnaires, voice recording 30 minutes
(Plus optional interview up to 60 minutes)

5. What are the possible benefits?

We do not know yet whether this voice therapy programme will benefit you directly. The information we get from this study may help us to plan a larger study to test how effective this voice therapy programme is for patients who are having surgery on their vocal folds.

6. What are the disadvantages?

We do not expect there to be any disadvantages or risks to you by taking part. We will arrange to complete questionnaires, do voice recordings and undertake the interview at times to suit you. We have talked to our patient groups about the questionnaires that we are asking you to fill in to make sure that we collect information that is helpful but not too burdensome for you.

7. How will we use information about you?

We will need to use information from you, and from your medical records for this research project.

This information will include your;

- initials
- NHS number
- Name
- contact details
- voice/throat symptoms and medical history
- voice recordings
- voice therapy and surgical notes

People will use this information to do the research or 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.

We will keep all information about you safe and secure

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 ask you to download a freely available voice recorder app onto your smartphone or tablet to record you reading a passage of text. We have chosen an app, Voice Record Pro, which makes high quality recordings of your voice which will then be analysed by the study team. You will send the voice recordings via email to the research team's secure NHS.net email. When you download this app, your IP address will be recorded and stored by the App developer in Canada. It is important to note that the laws about the protection of personal data in other countries may be not as strict as in this country. More information can be found on the App's privacy statement here: https://www.bejbej.ca/Privacy_Policy

Downloading an app to your personal device is entirely at your own risk. Nottingham University Hospitals NHS Trust does not guarantee the security of the app and takes no responsibility for the prevention from loss of, alteration of, or improper access to, your account information or data stored on your personal device. If you are not happy to download this app, we will ask you to come into your treating hospital to make recordings using the app on NHS Trust smartphone rather than your own device.

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.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

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

- at www.hra.nhs.uk/information-about-patients/

- our GDPR leaflet available on request from researchsponsor@nuh.nhs.uk; or by the following link www.nuh.nhs.uk/gdpr
- by asking one of the research team
- by emailing the Data Protection Officer for NUH at dpo@nuh.nhs.uk,
- by ringing the Data Protection Officer for NUH on 0115 924 9924 (extension 63975)
- by visiting www.nuh.nhs.uk/gdpr

8. What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally identifiable information possible.

9. What happens when the study is finished?

When the study ends, 6 months after the surgery on your vocal folds, you will continue with any prearranged follow up with your ENT Doctor and Speech and Language Therapist. Your involvement in the study will not affect any follow up care by your clinical team

If you would like to receive a summary of the research findings, you can state that you would like us to keep your contact details on file and send this to you when the study is completed

10. What if there is a problem?

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. If you remain unhappy and wish to complain formally, you can do this by contacting the study lead, Vicky Booth or the Patient Advice and Liaison Service (PALS).

Contact Details

Chief Investigator

Vicky Booth Tel: 07793 278581 Email: Vicky.booth@nuh.nhs.uk

PALS Nottingham Tel: 0800 183 0204 Email: PALS@nuh.nhs.uk

PALS Lewisham Tel: 020 8333 3355 Email: PALS.lewisham@nhs.net

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you

11. Further Information

You are encouraged to ask any questions you wish before, during or after your involvement in the study. If you have any questions about the study, please speak to the Investigators who will be able to provide you with up to date information about the study procedures involved. If you require any further information or have any concerns while taking part in the study, please contact the Investigators (both are listed at the top of this document). If you wish to read the research on which this study is based, please contact a member of the study team.

If you decide you would like to take part, then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your medical notes, and one will be filed with the study records. With your permission your GP (and other doctors who may be treating you) may be notified that you are taking part in this study.

12. Patient and Public Involvement

All research participants should be offered the opportunity to feedback on their experiences of taking part in clinical research at NUH through the Participant in Research Excellence Survey (PRES). This survey is managed by the NIHR Clinical Research Network and is open to all participants in NIHR-adopted research trials. This is optional.

The web link is: *www.nuh.nhs.uk/ri-feedback*

You can have more time to think this over if you are at all unsure.

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