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The Pre- and Post-Operative Voice therapy trial (PaPOV)

Submission date
22/12/2022

Recruitment status
No longer recruiting

Registration date
04/01/2023

Overall study status
Completed

Last Edited
16/01/2026

Condition category
Ear, Nose and Throat

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
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.

Who can participate?
Patients with a benign vocal fold lesion on their vocal fold who have been offered surgery

What does the study involve?
The study involves taking part in voice therapy sessions with a specialist speech and language therapist before and after the patient's surgery. The therapy can be done either face-to-face at the hospital or via a video link.

The therapy involves receiving information and advice about their voice, their surgery and their recovery. Participants are taught voice exercises to do in the session and at home to help to produce voice in a healthy way. Participants will be offered at least two sessions before and one session after their surgery but may receive more. This will be decided by the patient and their therapist depending on how much help they need and how well they are recovering.

Anyone taking part will also be asked to attend three additional appointments either virtually or face-to-face to complete some questionnaires and to make a recording of their voice. These appointments will be at the beginning of the study, 3 months after surgery and 6 months after surgery. Participants will also be invited to take part in an interview to share their experiences of the research and the voice therapy they received.

What are the possible benefits and risks of participating?
We do not yet know whether this voice therapy programme will benefit patients. The information we get from this study will 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.

We do not expect there to be any risks involved in taking part. We have talked to our patient group to make sure that any questionnaires we ask participants to do are relevant and are not too time-consuming. We will make appointment times to suit the participants.

Where is the study run from?
Nottingham University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2021 to October 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) Clinical Doctoral Research Fellow for Anna White, Ref: NIHR301570 (UK)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
295725

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
22ET004, IRAS 295725, CPMS 54591

Study information

Scientific Title
Pre and Post-Operative Voice therapy (PaPOV) for benign vocal fold lesions: Non-randomised, multicentre feasibility trial with nested process evaluation

Acronym
PaPOV

Study objectives
There are no clinical guidelines determining management for patients with benign vocal fold lesions (BVFLs). Patients may be offered surgery, pharmacological management, voice therapy, or a combination. Emerging research suggests that voice therapy delivered by a specialist speech and language therapist (SLT) pre and post-operatively gives greater improvement than surgery alone with pre-operative voice therapy resulting in avoidance of surgery in up to 50% of patients. However, it is unclear which elements of voice therapy are most effective when they should be introduced or with whom.

The Medical Research Council's framework for developing and evaluating complex interventions advocates a structured developmental pathway by undertaking preliminary intervention development work, followed by feasibility testing. This reduces the likelihood of research waste,

which, they describe as an inevitable consequence of failing to devote adequate time to developing, describing, and testing a complex intervention. Work has now been completed to identify the potential ingredients in a best-practice voice therapy intervention. This has involved the triangulation of findings from a systematic review, expert interview study, national survey of current practice, a Delphi consensus study and extensive PPI engagement activities.

We now have a Pre- and Post-Operative Voice Therapy intervention (PaPOV) which is described in detail, in accordance with the TIDieR checklist, and according to the Rehabilitation Treatment Specification System (RTSS) for voice. It is now appropriate to test the feasibility of delivering this intervention to patients who are undergoing phonosurgery for the removal of BVFLs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/12/2022, West London and GTAC Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8098, (0)207 104 8007, (0) 207104 8256; westlondon.rec@hra.nhs.uk), ref: 22/LO/0859

Study design
Mixed methods non-randomized multicentre feasibility trial with process evaluation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pre and post-operative voice therapy for patients with benign vocal fold lesions

Interventions
Participants will receive a voice therapy package, termed the Pre and Post-Operative Voice Therapy intervention (PAPOV). PAPOV includes a mix of information, education, advice and voice exercises. There are 7 core components to the intervention which all participants will receive and 4 additional components which clinicians will select following the assessment of participant requirements. Each component comprises a target and a number of described ingredients.

All participants will take part in a minimum of two pre-operative voice therapy sessions, delivered via telehealth or face-to-face by a speech and language therapist trained in the PAPOV intervention. Participants will be given information and advice about their voice, diagnosis and surgery. The clinician and participant will develop goals for the participant's voice and the participant will be taught exercises to help produce voice in a healthy way. Participants will be instructed to follow the advice and complete exercises between voice therapy sessions.
Following pre-operative voice therapy, the patient will come into the hospital to have the lesion removed from their vocal fold. All details related to the surgery will be undertaken by the hospital. The research team are not involved in the surgery.
Following surgery, participants will be invited to attend post-operative voice therapy. The number of sessions will vary depending on how the patient is recovering but is likely to be between one and four sessions. The aim is to support the patient in their recovery after their

operation and to improve the sound strength and stamina of the voice. Session length will vary according to patient need but sessions are likely to last between 30-60 minutes.

Intervention Type
Behavioural

Primary outcome(s)
The feasibility trial objectives are to gather data regarding the following parameters:
1. Number of eligible patients measured using the eligibility log and surgical lists at each site at the end of the study
2. Number of patients recruited and consented to the trial as a proportion of those eligible, measured using the eligibility log at each site at the end of the study
3. Number of patients completing the study as a proportion of those recruited measured using the case report form at the end of the study
4. The amount of clinical outcomes data completed measured using the case report form at each time point (baseline, 3 and 6 months post-surgery) (%)
5. The amount of health economics data completed measured using the case report form at each time point (baseline, 3 and 6 months post-surgery) (%)

Key secondary outcome(s))
Secondary outcome measures relate to the process evaluation:
1. Number of voice therapy sessions received by each patient measured using clinical notes at the end of the study
2. Level of adherence to the PaPOV intervention within voice therapy sessions measured as the number of essential components documented in clinical notes for each session
3. Description of any adaptations or alterations made to the PaPOV intervention measured using analysis of clinical notes for each session and analysis of clinician interviews
4. The amount and completeness of home practice measured using adherence questionnaire data completed by participants at the end of their voice therapy sessions
5. Description of participating sites and participants, measured using the Case Report Form at the end of the study
6. Understand clinicians' experiences of being trained to deliver the intervention and trial processes, measured using an analysis of clinician mentoring records and interview data with clinicians at the end of the study
7. Understand clinicians' experiences of delivering the intervention including acceptability, barriers and facilitators measured using analysis of clinician mentoring records and interview data with clinicians at the end of the study
8. Understand participants' experiences of trial processes measured using analysis of interview data at 6 months post-surgery
9. Understand participants' experiences of receiving the PaPOV intervention including acceptability, barriers and facilitators measured using analysis of interview data at 6 months

Completion date
31/10/2024

Eligibility

Key inclusion criteria
1. Patients with benign vocal fold lesions (BVFLs) who have been consented for phonosurgery by an ENT surgeon as part of their management
2. Aged 18 years old and over

3. Willing and able to offer informed consent
4. Presence of unilateral or bilateral benign vocal fold lesion on the vibrating portion of the vocal fold (including one or a combination of these diagnostic categories; fibrotic vocal fold nodules, polyp, cyst, pseudocyst, polypoid fringe, Reinke's odema, sulcus, mucosal bridge, papilloma);
5. Diagnosis confirmed using videolaryngostroboscopy
6. +/- presence of additional muscle tension dysphonia/inflammation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
41

Key exclusion criteria
1. Diagnosis of soft vocal fold nodules; these patients receive a different pathway of care
2. Diagnosis of arytenoid granuloma; this does not affect the vibratory portion of the vocal fold
3. Previous phonosurgery
4. Suspicion of malignancy requiring urgent microlaryngoscopy and biopsy

Date of first enrolment
09/01/2023

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
England
NG7 2UH

Study participating centre
Lewisham and Greenwich NHS Trust
University Hospital Lewisham
Lewisham High Street
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SE13 6LH

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

1. The datasets generated during and/or analysed during the current study are/will be available upon request from Vicky Booth (CI) vicky.booth@nottingham.ac.uk.
2. The datasets generated during and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary

Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/05/2024	04/06/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 2.0	01/12/2022	28/12/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (preprint)		23/05/2023	11/03/2024	No	No