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Understanding speech-related breathing behaviours in age-related voice disorder

Submission date
22/08/2024

Recruitment status
No longer recruiting

Registration date
19/11/2024

Overall study status
Ongoing

Last Edited
24/04/2025

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
This study aims to better understand the causes and potential treatments for presbyphonia, a voice disorder that affects older adults. While previous research has focused on the larynx, this study will examine the role of the respiratory system. Researchers will investigate how lung function, respiratory muscle strength and the management of breath support for speech relate to the individual's experience of voice problems. By comparing the breathing patterns of people with presbyphonia to normative data reported in the literature, the study hopes to identify specific targets for treatment and ultimately develop more effective interventions for this condition.

Who can participate?
People over the age of 50 years old with typical hearing and no cognitive impairment who have been diagnosed with presbyphonia by an ENT specialist, who have no other laryngeal or neurological diagnosis which can impact voice or breathing and who have not received speech and language therapy intervention for their voice within the last 12 months.

What does the study involve?
Participants will be screened over the phone to ensure they meet the criteria. If eligible, they will be invited to a two-hour appointment at the hospital, where they will undergo hearing, cognitive, breathing, voice, and speaking assessments. Participants will also be asked to complete questionnaires about their voice-related quality of life and any experience of breathlessness symptoms around speaking.

What are the possible benefits and risks of participating?
The information gathered aims to improve the understanding of presbyphonia and develop more effective treatments. The findings will be used to create a new therapy package that may improve voice quality and reduce the need for surgery.

All the investigations undertaken are non-invasive and should not cause discomfort. Some of them, however, require maximal effort and might be a bit tiring. The study team will ensure to pace activities and give adequate time to rest in between. In the process of investigating participant breathing, the researchers may identify the need for primary care physicians to

consider a referral to a lung specialist. Screening will also be carried out for hearing and cognitive skills, which might identify that further investigations into either of these areas are worth considering. Participants will be informed if the researchers inform their primary care physicians of their participation in this study if that is the case.

Where is the study run from?
The study is sponsored by University College London Hospitals (UCLH) NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
May 2024 to April 2027. This study is part of a larger, three-phase project, of which it is the first phase.

Who is funding the study?
The NIHR Academy, as part of a Doctoral Clinical and Practitioner Academic Fellowship (DCAF) award.

Who is the main contact?
Mr Brian Saccente-Kennedy, the Chief Investigator and DCAF Fellow, brian.saccente-kennedy@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
328486

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 56137, IRAS 328486, NIHR303555

Study information

Scientific Title
CLEARER: A Combined LaryngEAl and REspiratory AppRoach to Presbyphonia Voice Therapy

Acronym
CLEARER - Phase One

Study objectives
Our null hypothesis is as follows:
H0: The speech-breathing patterns of people with presbyphonia will be no different from published data for age-matched non-voice-disordered males and females.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/08/2024, London – West London & GTAC Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 20 7104 8202; westlondon.rec@hra.nhs.uk), ref: 24/PR/0948

Study design
Observational cross-sectional

Primary study design
Observational

Study type(s)
Other

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

Interventions
This cross-sectional observational study is the first phase of a multiphase project to design and test the feasibility of a novel combined laryngeal and respiratory-focused treatment for presbyphonia. This phase seeks to characterise the respiratory presentation and speech-related breathing patterns of people with presbyphonia and identify how these correlate with the subjective experience of vocal handicap.

Potential participants will be identified from voice-specialist ENT clinics at four London NHS Trusts (University College London Hospitals (UCLH), Guy's Hospital, Northwick Park Hospital and Lewisham University Hospital) where the initial diagnosis of presbyphonia will be made by an ENT consultant surgeon. During routine care at these voice clinics, high-quality images of participant larynges will be recorded as per local Trust policy. Participants will be approached

with information about the present study by a member of their clinical team (speech therapist or ENT consultant), and permission sought to pass their details on to the research team (see later section on recruitment).

The study aims to recruit 14 males and 21 females as this number of participants is predicted to give sufficient power (0.8) in both groups to detect a minimum clinically significant difference in speech breathing metrics from published data (which is stratified by sex) using a two-sided single-sample t-test. Recruitment and data collection are expected to take place over 7 months. Audit data from the four PIC sites predicts that this will require approximately 50% of all identified people with presbyphonia to take part in the study, however, participants may also be drawn from current patients on waiting lists for voice therapy, increasing the number of potential participants.

Data collection will take place in a single 2-hour research session at the Royal National ENT Hospital (UCLH). The session will include non-invasive procedures including breathing tests (spirometry), speech-breathing assessment (inductive plethysmography), voice assessment (audio and aerodynamic assessment), and answering standardised questionnaires relating to voice and breathing. Laryngeal visualisation will be achieved by accessing existing images/videos recorded at the point of participant identification by clinical teams during usual care.

Data collection and analysis will be conducted by the PhD student. Any subjective data analysis (such as auditory-perceptual voice assessment and visual assessment of laryngeal images) will be carried out by 4 clinicians with at least 10 years of experience in such analysis and who are blinded to participant characteristics.

To explicitly involve patients and their families as partners in my research, 10 older patients with presbyphonia (or their partners) were interviewed on their experience of living with their voice disorder, their desires for research, and the acceptability of the proposed study. The input of individuals was proactively sought from diverse and minoritised groups; 40% of my participants were from a BAME background, 10% identified as LGBTQ, and a wide range of educational and socioeconomic backgrounds were also represented.

Patient partners identified some of the outcome measures of interest in this study (the need for expert-rated auditory-perceptual voice quality, age-appropriate voice-related quality of life measures) and their input helped to identify the number and location of research sites (acceptable travel distances) and their desire for having the data acquired in one session. They felt the planned investigations and the likely travel distance from home (in the catchment areas of the four research sites) were likely to be acceptable to potential participants. Also, as all PPI members have, themselves, undergone all the investigations proposed by this study during their care in our team, they felt that research participants would both understand and accept these activities.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)

Lung volume initiation relative to end-expiratory level (LVI-R) measured in % of vital capacity (% VC) for reading and extemporaneous speech in comfortable and loud conditions measured using inductive respiratory plethysmography collected once during the research visit

Key secondary outcome(s))

The following secondary outcome measures will be collected during the research visit:
1. Lung volume termination relative to end-expiratory level (LVT-R) measured in % of vital capacity (%VC) for reading and extemporaneous speech in comfortable and loud conditions using inductive respiratory plethysmography
2. Lung volume excursion in %VC for reading and extemporaneous speech in comfortable and loud conditions measured using inductive respiratory plethysmography
3. Vital capacity expended per syllable (%VC/syl) for reading and extemporaneous speech in comfortable and loud conditions measured using inductive respiratory plethysmography
4. Ribcage contribution to lung volume excursion (in %) for reading and extemporaneous speech in comfortable and loud conditions measured using inductive respiratory plethysmography
5. Rate of speech (in syllables/second) for reading and extemporaneous speech in comfortable and loud conditions measured using acoustic signal and voice-to-text recognition algorithms
6. Utterance length (in syllables) for reading and extemporaneous speech in comfortable and loud conditions measured using acoustic signal and voice-to-text recognition algorithms
7. Vital capacity (in litres) measured using office-based spirometry
8. Forced vital capacity (in litres), FVC, measured using office-based spirometry once during the research visit
9. Peak expiratory flow (in litres/second), PEF, measured using office-based spirometry once during the research visit
10. Forced volume in one second (in litres), FEV1, measured using office-based spirometry once during the research visit
11. Maximum expiratory pressure (in cmH2O) measured using an office-based respiratory muscle strength assessment device
12. Maximum inspiratory pressure (in cmH2O) measured using an office-based respiratory muscle strength assessment device
13. Laryngeal resistance (in cmH2O/l/s) measured using phonatory aerodynamic assessment equipment once during the research visit
14. Acoustic voice quality measured using the Acoustic Voice Quality Index (AVQI) once during the research visit
15. Auditory-perceptual voice quality measured using the Consensus Auditory-Perceptual Evaluation of Voice (CAPE-V) on voice samples recorded during the research visit
16. Patient perception of vocal-related quality of life measured using the Aging Voice Index (AVI), collected once during the research visit
17. Patient perception of breathlessness measured using the University of Cincinnati Dyspnea Questionnaire, collected once during the research visit

Completion date

30/04/2027

Eligibility

Key inclusion criteria

1. 50 years of age or older
2. Ear, nose and throat (ENT) consultant-confirmed diagnosis of presbyphonia
3. Laryngeal images available for analysis

4. Typical hearing (as indicated by hearing screening at 40 dB HL at 500, 1000 and 1500Hz, bilaterally).
5. Willing and able to offer informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Upper age limit
110 years

Sex
All

Key exclusion criteria
1. Recent (< 12 months) voice therapy
2. Diagnosis of a neurological condition affecting laryngeal or respiratory function (i.e. Parkinson's disease, CVA, spasmodic dysphonia)
3. Diagnosis of additional laryngeal pathology
4. Contraindicated for spirometry
5. Failing cognitive screen (< 23 on the Rowland Universal Dementia Assessment Scale, RUDAS)

Date of first enrolment
02/09/2024

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospital
250 Euston Road
London
United Kingdom
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Study participating centre
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre
University Hospital Lewisham
Lewisham High Street
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SE13 6LH

Study participating centre
Charing Cross Hospital
Fulham Palace Road
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Study participating centre
The Whittington Hospital
Highgate Hill
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N19 5NF

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust

ROR
https://ror.org/042fqyp44

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
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date