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Development of a standardised non-medical treatment for inducible laryngeal obstruction

Submission date
23/01/2024

Recruitment status
No longer recruiting

Registration date
25/01/2024

Overall study status
Completed

Last Edited
25/10/2024

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
Inducible laryngeal obstruction (ILO) is when the larynx (voice box) inappropriately closes. This leads to breathing difficulties and individuals may seek help from primary care, emergency departments or need to be admitted to hospital. Currently there is no standard approach to treat ILO once it is diagnosed. Non-pharmacological interventions (treatment without medication) are often recommended and used in the clinical setting but is not yet known what the possible key components of non-pharmacological interventions are and whether they are acceptable to individuals with ILO. The aim of this study is to develop and describe a non-pharmacological standardised intervention for adults with ILO.

Who can participate?
1. Healthcare professionals experienced in assessing, diagnosing and delivering non-pharmacological interventions to adults with ILO (defined as holding a regular ILO caseload of >3 years)
2. Patients aged over 18 years with an established diagnosis of ILO based on clinical evaluation and endoscopic visualisation of laryngeal obstruction during a symptomatic episode.

What does the study involve?
It will be in three phases:
Stage 1: A 60-90-minute focus group with 5-7 health care professionals will be held virtually. It will explore attitudes and beliefs on the timing of ILO intervention, how much should be given, how and what should be delivered. The meeting will be transcribed and analysed for any themes.
Stage 2: One-to-one (30-45 minutes) interviews with 20-27 patients diagnosed with ILO, will explore patient opinion on interventions. An interview guide will be developed based on Stage 1. The meetings will be held virtually, transcribed, and then analysed. Following analysis, a draft of a standardised non-pharmacological intervention for adults with ILO will be prepared.
Stage 3: The draft manual will be shown to participants from Stages 1 and 2, together with a questionnaire to check for content, understanding and acceptability. Based on feedback, any required changes will be made and a final manual produced.

What are the possible benefits and risks of participating?
Taking part in the study will have no direct benefit to participants. There are no identified significant risks to taking part. The study will not explore patients' experience of living with ILO.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
September 2023 to December 2024

Who is funding the study?
1. Manchester Biomedical Research Centre (UK)
2. North West Lung Centre Charity (UK)

Who is the main contact?
Jemma Haines, jemma.haines@mft.nhs.uk

Contact information

Type(s)
Public, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
335820

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 335820, Sponsor reference NHS002135

Study information

Scientific Title
Inducible Laryngeal Obstruction in adults: developing a standardised non-pharmacological Intervention

Acronym
ILO-i

Study objectives
Currently there is no standard approach to treat Inducible Laryngeal Obstruction (ILO) once it is diagnosed. There are no licenced medications available and non-pharmacological interventions (treatment without medication) are often recommended in a clinical setting.

The purpose of this research is to understand what the possible key components of non-pharmacological interventions are and whether they are acceptable to individuals with ILO.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/02/2024, North West Greater Manchester South (3rd Floor, Barlow House, 4 Minshull Street, HRA NRES Centre, Manchester, M1 3DZ, United Kingdom; +44 (0)20711048014; gmsouth.rec@hra.nhs.uk), ref: 24/NW/0010

Study design
Single-centre qualitative interview and questionnaire study

Primary study design
Observational

Secondary study design
Qualitative study

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Inducible Laryngeal Obstruction in adults

Interventions
Stage 1: A 60-90 minutes focus group (with 5-7 experienced health care professionals experienced in delivering non-pharmacological interventions to adults with ILO)

Stage 2: One-to-one (30-45 minutes) interviews with 20-27 patients diagnosed with ILO

Stage 3: The draft manual will be shown to participants from Stage 1 and 2, together with a bespoke questionnaire to check for content, clarity and acceptability. Based on feedback, any required changes will be made and a final manual produced.

Intervention Type
Other

Primary outcome measure
Participant opinions/responses (variable) to questions regarding non-pharmacological interventions for ILO will be measured in a focus group/interview at a single timepoint using data transcript thematic analysis

Secondary outcome measures
Participant responses (variable) to a debriefing questionnaire on a draft standardised treatment manual for ILO will be measured at a single timepoint using thematic analysis

Overall study start date
23/09/2023

Completion date
31/12/2024

Eligibility

Key inclusion criteria

Healthcare professionals:
1. Experienced (defined as holding a regular ILO caseload for >3 years) in assessing, diagnosing and delivering nonpharmacological treatment to adults with ILO

Treatment naïve patients:
1. An established diagnosis of ILO based on i) clinical evaluation AND ii) endoscopic visualisation of laryngeal obstruction during a symptomatic episode
2. >18 years old
3. Have not received and completed non-pharmacological / behavioural therapy intervention for ILO

Post-treatment patients:
1. An established diagnosis of ILO based on i) clinical evaluation and ii) endoscopic visualisation of laryngeal obstruction during a symptomatic episode
2. >18 years old
3. Have received and completed a non-pharmacological behavioural therapy intervention for ILO

Participant type(s)
Patient, Health professional

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
Total target recruitment of participants: 34 (healthcare professionals: 5-7; treatment naïve patient participants 5-7; patients post treatment 15-20).

Key exclusion criteria
Healthcare professionals:
1. Healthcare professionals who have no specialist experience in assessing, diagnosing and delivering nonpharmacological treatment to adults with ILO

Treatment naïve patients:
1. Have received any previous therapy intervention for ILO, refractory chronic cough or upper airway symptoms (e.g.
muscle tension dysphonia, globus pharyngeaous)
2. Have uncontrolled asthma airway inflammation or obstruction (defined as fractional exhaled nitric oxide >50ppb,
FEV1/FVC <70%)

Post-treatment patients:
1. Have completed a non-pharmacological behavioural therapy intervention for ILO greater than

4 months prior to study
2. Have uncontrolled airway inflammation or obstruction (defined as fractional exhaled nitric oxide >50ppb, FEV1/FVC
<70%)

Date of first enrolment
01/03/2024

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester University NHS Foundation Trust
Wythenshawe Hospital
Southmoor Road
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United Kingdom
M23 9LT

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
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United Kingdom
S5 7AU

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
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B15 2GW

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Royal Preston Hospital
Sharoe Green Lane
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PR2 9HT

Sponsor information

Organisation
University of Manchester

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Sponsor type
University/education

Website
http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Manchester Biomedical Research Centre

Alternative Name(s)

NIHR Manchester Biomedical Research Centre, Manchester BRC, NIHR Manchester BRC, NIHR Manchester Biomedical Research Unit, Manchester NIHR BRC, Manchester NIHR Biomedical Research Centre, Biomedical Research Centre, BRC, NIHR BRC

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Funder Name
North West Lung Centre Charity

Results and Publications

Publication and dissemination plan
It is intended the results of the study will be published in a doctoral thesis, high-impact peer-reviewed journals and presented at conferences so that we can explain to the healthcare community what our research results have shown. Direct quotes from one-to-one conversations may be used in the publication of results but these will be anonymised. Following the end of the study a general newsletter will be available to all participants who took part in the study.

Intention to publish date
01/05/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Jemma Haines (jemma.haines@mft.nhs.uk).

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 file	version 1.3	19/01/2024	24/01/2024	No	No