

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

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<b>Registration date</b> 25/01/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/10/2024	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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](mailto:jemma.haines@mft.nhs.uk)

## Contact information

### Type(s)

Public, Principal investigator

### Contact name

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### Type(s)

Scientific

### Contact name

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

335820

### **ClinicalTrials.gov (NCT)**

Nil known

### **Protocol serial number**

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**

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### **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

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s)**

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

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

18 years

### **Upper age limit**

99 years

### **Sex**

All

### **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 pharyngeaus)

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**

United Kingdom

England

## **Study participating centre**

**Manchester University NHS Foundation Trust**

Wythenshawe Hospital

Southmoor Road

Wythenshawe

Manchester

United Kingdom

M23 9LT

## **Study participating centre**

**Sheffield Teaching Hospitals NHS Foundation Trust**

Northern General Hospital

Herries Road

Sheffield

United Kingdom

S5 7AU

## **Study participating centre**

**University Hospitals Birmingham NHS Foundation Trust**

Queen Elizabeth Hospital

Mindelsohn Way

Edgbaston

Birmingham

United Kingdom

B15 2GW

## **Study participating centre**

**Lancashire Teaching Hospitals NHS Foundation Trust**

Royal Preston Hospital

Sharoe Green Lane

Fulwood

Preston

United Kingdom

PR2 9HT

## **Sponsor information**

**Organisation**

University of Manchester

**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****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](mailto: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?
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<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>	version 1.3	19/01/2024	24/01/2024	No	No