

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

Submission date	Recruitment status	[X] Prospectively registered
23/01/2024	No longer recruiting	[X] Protocol
Registration date	Overall study status	[] Statistical analysis plan
25/01/2024	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
22/01/2026	Ear, Nose and Throat	

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

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

335820

ClinicalTrials.gov (NCT)

Nil known

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

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)

Health professional, Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

99 years

Sex

All

Total final enrolment

0

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 pharyngeous)

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

England

M23 9LT

Study participating centre

Sheffield Teaching Hospitals NHS Foundation Trust

Northern General Hospital

Herries Road

Sheffield

England

S5 7AU

Study participating centre

University Hospitals Birmingham NHS Foundation Trust

Queen Elizabeth Hospital

Mindelsohn Way

Edgbaston

Birmingham

England

B15 2GW

Study participating centre

Lancashire Teaching Hospitals NHS Foundation Trust

Royal Preston Hospital

Sharoe Green Lane

Fulwood

Preston

England

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).

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?
Results article		10/06/2025	22/01/2026	Yes	No
Protocol file	version 1.3	19/01/2024	24/01/2024	No	No