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Is complete decongestive therapy a feasible and acceptable intervention for patients with lymphoedema following treatment for head and neck cancer?

Submission date
27/07/2026

Recruitment status
Recruiting

Registration date
03/08/2026

Overall study status
Ongoing

Last Edited
03/08/2026

Condition category
Cancer

[ ] 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
People treated for head and neck cancer can experience long-term side effects after treatment. One of these is head and neck lymphoedema, which is swelling caused by a build-up of fluid in the tissues of the head and neck. This swelling can affect swallowing, eating and drinking, appearance, comfort, and overall quality of life.
The RELIEF-HNC study aims to improve care for people with head and neck lymphoedema. Researchers want to learn more about patients' experiences and identify the best ways to manage this condition. The study will look at whether a treatment called Complete Decongestive Therapy (CDT) is practical, acceptable and helpful for reducing swelling and improving swallowing.
The study has three parts over three years. First, researchers will review existing evidence about CDT. Second, patients, carers and healthcare professionals will work together to design and improve a treatment programme. Third, the treatment programme will be tested in a small feasibility study to see how well it works in practice.

Who can participate?
Different groups can take part in different parts of the study.
For the workshops, adults who have symptoms of head and neck lymphoedema after treatment for head and neck cancer can take part. Participants may also invite a carer, family member or other person who supports them.
Healthcare professionals with experience of caring for people with head and neck cancer and/or lymphoedema can also take part in workshops. This includes doctors, nurses, speech and language therapists, physiotherapists, radiographers, psychologists and other members of the multidisciplinary team.
For the feasibility study, participants must have head and neck lymphoedema and swallowing difficulties following treatment for head and neck cancer.

What does the study involve?
People taking part in the patient and carer workshops will attend two or three group meetings at University Hospital Coventry. During these workshops, participants will discuss their experiences, review treatment materials and help design a therapy programme that is practical and patient-centred.
Healthcare professionals will take part in two online workshops lasting about 1 hour each. They will discuss current care, barriers to treatment and ways of introducing the therapy programme into practice.
Participants in the feasibility study will be assigned by chance to one of two treatment groups. One group will receive CDT at University Hospital Coventry. The other group will receive lymphoedema treatment at Myton Hospice.
Those receiving CDT will attend three appointments. At the first appointment, researchers will assess swallowing and lymphoedema, take photographs, collect measurements and teach participants a personalised home treatment programme. The second appointment includes a swallowing X-ray. Participants will then carry out their treatment programme at home for 3 months. At the third appointment, researchers will repeat the assessments to see whether there have been any changes.
Some participants may also be invited to take part in a one-off interview lasting around 40 to 60 minutes to discuss their experiences of the treatment and the study.

What are the possible benefits and risks of participating?
Taking part may not provide a direct benefit. However, participants may feel positive about helping improve future care for people affected by head and neck cancer and lymphoedema. Researchers hope that CDT may reduce swelling and improve swallowing, although this cannot be guaranteed.
The workshop and interview parts of the study carry very few risks. Some people may find it upsetting to talk about their experiences of cancer treatment. Support information can be provided if needed.
The treatment programme has been designed to be safe and will only be offered to people who are suitable for it. People with certain medical conditions that could increase the risk of complications will not be included. Participants can stop taking part at any time.
Swallowing X-rays used in the study are already part of routine care and do not involve extra procedures beyond normal treatment.

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

When is the study starting and how long is it expected to run for?
May 2026 to March 2028.

Who is funding the study?
The study is funded by the National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
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Professor Jo Patterson, joanne.patterson@liverpool.ac.uk

Contact information

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Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
344718

Central Portfolio Management System (CPMS)
62908

Study information

Scientific Title
RELIEF-HNC: Is complete decongestive theRapy a fEasibLe and acceptable IntervEntion for patients with lymphoedema Following treatment for Head and Neck Cancer?

Acronym

RELIEF-HNC

Study objectives
1. Perform an up-to-date systematic review on the effectiveness of CDT as an intervention in HNL patients to improve dysphagia outcomes
2. Co-production to refine intervention. Address challenges identified in pre-feasibility pilot testing and potential solutions for HNC survivors' eligibility, recruitment, adherence, compliance and retention rates. This will include uptake time point in their HNC pathway, intervention components and fidelity
3. Explore the mechanism of action of intervention delivery using programme theory with an embedded behaviour change framework
4. Test candidate outcome measures on quality of life (QOL),patient reported swallowing outcomes measures, objective swallowing outcome measures, and volumetric analysis of HNL
5. Obtain HNC survivors' and professionals' perspectives on acceptability of the intervention, study processes and integration into usual care using a nested qualitative sub-study
6. Determine a power calculation for future RCT
7. Obtain preliminary estimate of intervention cost

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/02/2026, Health and Social Care Research Ethics Committee A (HSC REC A) (Office for Research Ethics Committees Northern Ireland (ORECNI) BSO, Floor 2, James House, 2-4 Cromac Avenue, BELFAST, BT7 2JD, United Kingdom; +44 28 95 361400; reca@hscni.net), ref: 26 /NI/0008

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Head and neck cancer

Interventions

Study design
This project comprises three workstreams:
1. Systematic review to inform intervention development
2. Co-production workshops using a Living Labs approach to design and refine the intervention
3. A single-centre randomised feasibility study comparing a personalised complete decongestive therapy (CDT) intervention with usual care in patients with head and neck lymphoedema (HNL) following head and neck cancer treatment

Randomisation
Participants in the feasibility study are randomised after providing informed consent.
Randomisation method: • Telephone-based digital randomisation system • Allocation occurs after consent is obtained • Participants randomised to the control arm are referred to the local community-based lymphoedema service
No sealed-envelope process is described.

Intervention arm
Participants receive a structured but individualised 3-month CDT programme delivered by a trained speech and language therapist who is also a certified lymphoedema therapist.
The intervention includes four core CDT components:
1. Manual lymphatic drainage (MLD), including intra-oral and external techniques tailored to the individual's lymphoedema profile
2. Compression therapy using chin straps, customised pads, garments, or kinesiotape where appropriate
3. Skin care education and management
4. Therapeutic exercises, including swallowing exercises

Intervention schedule:
• Baseline videofluoroscopy assessment (approximately 1 hour)
• Baseline assessment and development of an individualised CDT programme (approximately 2 hours)
• Provision of personalised compression garments and self-management materials where indicated
• Daily home programme of MLD and exercises
• Compression therapy at least 3 times per week, daily if tolerated
• Follow-up review at 1 week (approximately 30 minutes)
• Final review and repeat assessments at 3 months (approximately 2-3 hours)
Participants also receive written self-management resources and routine clinical follow-up.

Control arm
Participants receive usual standard care for HNL from a West Midlands community-based lymphoedema service.
Usual care may include:
• Manual lymphatic drainage
• Compression therapy
• Kinesiotape
• Compression garments
• Other routine lymphoedema management strategies
However, treatment is delivered according to standard clinical practice and is not guided by the structured CDT protocol used in the intervention arm. No additional treatment requirements are imposed.

Duration of intervention and follow-up
Intervention arm:
• Active intervention duration: 3 months (12 weeks)
• Follow-up assessment: at 3 months following baseline
Control arm:
• Usual care delivered over the same study period
• Baseline and post-treatment assessments conducted at 3 months
All participants:
• Outcome measures collected at baseline and approximately 3 months (12 weeks)
• Nested qualitative interviews may occur during or after the intervention period

Co-production phase
Prior to the feasibility study, the intervention is developed through three phases of co-production workshops conducted between April 2026 and August 2026:
1. Co-design workshops to identify priorities, barriers and facilitators
2. Co-production workshops to refine the intervention and implementation strategy
3. Co-customisation workshops to finalise the intervention and supporting resources
The final CDT intervention tested in the feasibility study is derived from this co-production process.

Intervention Type
Other

Primary outcome(s)
Feasibility outcomes:
1. Acceptability and appropriateness of the intervention and outcome measures measured using qualitative semi-structured interviews and reflexive thematic analysis during the intervention and after the intervention
2. Acceptability of the study protocol measured using qualitative semi-structured interviews and reflexive thematic analysis during the intervention and after the intervention
3. Understanding of the mechanism of change measured using qualitative semi-structured interviews and reflexive thematic analysis during the intervention and after the intervention
4. Contextual factors influencing intervention delivery and participation measured using qualitative semi-structured interviews and reflexive thematic analysis during the intervention and after the intervention
5. Number of patients screened measured using the study screening log throughout the recruitment period
6. Number of eligible and ineligible patients and reasons for ineligibility measured using the study screening log throughout the recruitment period
7. Number of patients agreeing to participate and associated timepoint measured using study recruitment records throughout the recruitment period
8. Reasons for refusal to participate measured using study recruitment records at the point of recruitment approach
9. Number of patients retained in the study measured using study retention records at follow-up
10. Reasons for withdrawal from the study and timepoint of withdrawal measured using study withdrawal records throughout study participation
11. Adverse events measured using adverse event reporting records throughout study participation
12. Intervention fidelity measured using a fidelity checklist used to record and standardise

consultations and document deviations at each intervention consultation
13. Intervention adherence measured using a daily tick-box diary daily throughout the intervention period

Key secondary outcome(s)
1. Lymphoedema-related quality of life measured using the Comprehensive Assessment of Lymphedema Impact in the Head and Neck (CALI-HaN) questionnaire at baseline, 3 months and 12 months
2. Swallowing-related quality of life measured using the MD Anderson Dysphagia Inventory (MDADI) at baseline, 3 months and 12 months
3. Swallowing performance and functional status measured using the Performance Status Scale for Head and Neck Cancer Patients (PSS-HN) at baseline, 3 months and 12 months
4. Swallowing function measured using the 100-mL Water Swallow Test (bedside timed swallow test) at baseline, 3 months and 12 months
5. External head and neck lymphoedema severity measured using the MD Anderson Cancer Center Head and Neck Lymphedema (HNL) Rating Scale through palpation at baseline, 3 months and 12 months
6. Pharyngeal swallowing function and dysphagia severity measured using videofluoroscopic swallow study (VFSS) and the Dynamic Imaging Grade of Swallowing Toxicity (DIGEST) rating scale at baseline, 3 months and 12 months
7. Internal lymphoedema severity measured using flexible nasendoscopy (FNE) and the Patterson Oedema Rating Scale at baseline, 3 months and 12 months
8. Tissue fluid content in the head and neck region measured using tissue dielectric constant assessment with the LymphScanner device at baseline, 3 months and 12 months
9. Superficial tissue induration and skin stiffness measured using the Skin Fibrometer at baseline, 3 months and 12 months
10. External appearance of head and neck lymphoedema measured using standardised digital photographs taken from frontal, lateral, neck extension and neck flexion positions at baseline, 3 months and 12 months
11. Intervention frequency, intensity and duration measured using digitally recorded intervention delivery data pre-intervention and post-intervention

Completion date
01/04/2028

Eligibility

Key inclusion criteria
1. Patients with a HNC diagnosis
2. Patients presenting with Stage 1a oedema or above. Surgical patients at least 8 weeks post treatment
3. Oncology patients at least 8 weeks post chemo-radiation. 50 Gy or higher dose of radiation to bilateral neck and primary tumour site in 30 or more fractions
4. Aged 18 years or older
5. All genders

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Medical contraindications
2. Patients with active/recurrent HNC disease
3. Patient who are unable to provide informed consent
4. Patients with head and neck lymphedema from non cancer aetiologies

Date of first enrolment
01/05/2026

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
United Kingdom

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
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Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.6	24/04/2026	29/07/2026	No	No