ISRCTN13855775 https://doi.org/10.1186/ISRCTN13855775

Getting recovery from head and neck cancer right after neck dissection

Submission date
18/12/2024

Recruitment status
Recruiting

Registration date
20/12/2024

Overall study status
Ongoing

Last Edited
06/10/2025

Condition category
Cancer

[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
Head and neck cancer affects the mouth, throat, salivary glands, voice box, nose or sinuses. Every year over 12,000 people get head and neck cancer. It is the 8th most common form of cancer. Over recent years many more people, particularly young people, have developed head and neck cancers. Many of these cancers are removed surgically. Some people also need radiotherapy or chemotherapy. Treatments are improving and better at getting rid of these cancers. Neck dissection is a common operation for this. This involves an operation to remove the lymph nodes in the neck. Many people having neck dissection have poor shoulder and neck movements, pain, fatigue and low mood afterwards. Only half ever return to work. The best way to help people recover after this operation is unknown. The study team want to find out whether physiotherapy treatment after neck dissection for these cancers helps people recover better. A small (pilot) study followed 36 people who had a neck dissection as part of their treatment. Half were offered extra physiotherapy after surgery. The other half had normal NHS care without extra physiotherapy. The extra physiotherapy treatment included neck and shoulder exercises, education on how to manage pain and relaxation techniques to help cope with fatigue and anxiety. This physiotherapy treatment was known as the GRRAND programme. The study was a success, with people who took part appreciating the extra treatment. The team now want to find out in a bigger study if the GRRAND programme helps patients and if it is good value for money for the NHS.

Who can participate?
Adult patients aged 18 years and older who are having a neck dissection operation as part of their treatment for head and neck cancer can participate at least 12 NHS hospitals in the UK

What does the study involve?
The study will randomly allocate participants to either: (1) usual NHS care which is physiotherapy assessment in a hospital and a leaflet providing advice on basic exercises; OR (2) usual NHS care PLUS the GRRAND physiotherapy programme.

The study will compare how well people recover, and their overall quality of life after a year in each group and work out how much each treatment costs. This will confirm whether the GRRAND programme helps people recover better after neck dissection for head and cancers,

and if it is good value for the NHS. The team will also interview patient participants and physiotherapists delivering the GRRAND programme to understand how it may work in the NHS.

What are the possible benefits and risks of participating?
The study will find out if offering a personalised physiotherapy programme after neck dissection for people with head and neck cancer is clinically beneficial and cost-effective to the NHS. There may not be any benefit in taking part in this study, research like this helps to continually improve the treatments and care provided to all patients now and in the future by collecting information on what may or may not help.

There are only minimal risks involved in this research. There is a possible risk of feeling a little sore after exercising as part of the physiotherapy rehabilitation. However, participants will be guided by their physiotherapist and will be able to seek their advice on managing any soreness and activities will be modified if needed.

Where is the study run from?
The study is being run from the Warwick Clinical Trials Unit at the University of Warwick. The qualitative study and process evaluation component of the study is being led by the University of Exeter.

When is the study starting and how long is it expected to run for?
September 2024 to March 2028

Who is funding the study?
National Institute for Health Research (NIHR) (UK) as part of the Health Technology Assessment (HTA) Programme funding stream.

Who is the main contact?
GRRAND email address: grrand@warwick.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-physiotherapy-after-surgery-for-head-and-neck-cancer-grrand

Contact information

Type(s)
Principal investigator

Contact name
Prof Toby Smith

ORCID ID
https://orcid.org/0000-0003-1673-2954

Contact details
Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, Giblet Hill Road
Coventry
United Kingdom
CV4 7AL
-
toby.o.smith@warwick.ac.uk

Type(s)
Principal investigator

Contact name
Prof Stuart Winter

ORCID ID
https://orcid.org/0000-0002-8152-816X

Contact details
Nuffield Department of Surgical Sciences
John Radcliffe Hospital
Headington
Oxford
United Kingdom
OX3 9DU
-
stuart.winter@nds.ox.ac.uk

Type(s)
Public, Scientific

Contact name
Mrs Chrissy Evans

Contact details
Warwick Medical School
Coventry
United Kingdom
CV4 7AL
-
grrand@warwick.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
333106

Protocol serial number
NIHR158902, SOC.20 23-24, CPMS 58043

Study information

Scientific Title
Getting Recovery Right After Neck Dissection for head and neck cancer (GRRAND)

Acronym
GRRAND

Study objectives
What is the clinical and cost-effectiveness of a personalised, physiotherapy-led, rehabilitation intervention (the GRRAND programme) compared to best practice NHS, post-discharge care for adults undergoing neck dissection for head and neck cancer?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/11/2024, London - Brent NHS Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048128, (0)207 104 8117, (0) 2071048131; brent.rec@hra.nhs.uk), ref: 24/LO/0722

Study design
Two-arm multi-centre pragmatic randomized controlled trial with internal pilot integrated health economic evaluation and process evaluation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rehabilitation after neck dissection for head and neck cancer

Interventions
1. Control Group (Best Practice NHS Post-Discharge Care)
Treatment Given: Routine NHS care including ward-based physiotherapy (respiratory care, positioning, walking, activities of daily living, neck and shoulder exercises) supplemented by a leaflet.
Total Duration of Treatment: Initial physiotherapy within the first 24 hours postoperatively, with no further physiotherapy unless deemed necessary by the ward physiotherapist or surgical team.
Follow-Up: Participants will be advised to continue exercises provided pre-hospital discharge and remain physically active. Follow-up assessments at baseline, six weeks, six months, and 12 months post-randomisation.
Randomisation Process: Participants will be randomised after verifying eligibility post-surgery. The specific method of randomisation (e.g., online tool, sealed envelope) is not detailed in the provided information.

2. Experimental Group (GRRAND Programme)
Treatment Given: Routine NHS care as described for the control group, plus a personalised physiotherapy intervention (up to six, one hour sessions) provided by a GRRAND-trained physiotherapist. The intervention includes range of motion exercises, progressive resistance exercises, education and advice on positioning, oral health, pain management, exercise adherence, return to work and normal activities, scar management, and education on fatigue, anxiety, and sleep hygiene.
Total Duration of Treatment: Up to six sessions of physiotherapy, each lasting 60 minutes.

Follow-Up: Similar follow-up assessments as the control group at baseline, six weeks, six months, and 12 months post-randomisation.
Randomisation Process: Same as the control group, with randomisation occurring after verifying eligibility post-surgery.

Intervention Type
Behavioural

Primary outcome(s)
Shoulder pain and function measured using the participant-reported Shoulder Pain and Disability Index (SPADI) questionnaire (total score) at 12 months

Key secondary outcome(s))
The following secondary outcome measures are assessed at 6 weeks, 3, 6 and 12 months unless specified otherwise:
1. Shoulder pain and function measured using the SPADI total score (secondary outcomes at 6 weeks and 6 months only)
2. Pain, function and disability subdomains measured using the individual SPADI domains
3. Health-related quality of life measured using the EQ-5D-5L*; EORTC cancer-specific questionnaires (C30(core); H&N35 (head and neck-specific
4. Mental wellbeing measured using the Short Warwick-Edinburgh Mental Wellbeing Scale
5. Exercise adherence measured using the Exercise Adherence Rating Scale at 6 weeks only
6. Adverse events including surgical complications*
7. Health resource use measured using a questionnaire*

(*3-month assessment for adverse events, EQ-5D-5L and health utilisation questionnaire only)

The study will also conduct a process evaluation including qualitative interviews of participants and physiotherapists to wider experiences, perceptions, reach and implementation of the trial and treatments from a patient and physiotherapist perspective.

Completion date
28/02/2028

Eligibility

Key inclusion criteria
1. People aged 18 years or over
2. Diagnosis of HNC with requirement for a neck dissection as part of their treatment with curative intent. Including those undergoing completion neck dissection following positive sentinel node biopsy or open neck node biopsy.
3. Able to attend out-patient physiotherapy appointments.
4. Provide informed consent.

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
1. People for whom intensive post-discharge physiotherapy is expected (e.g., scapula/scapula tip and/or latissimus dorsi free flaps or components thereof). This constitutes 3-5% of the neck dissection population and clinical equipoise regarding the role of physiotherapy is less evident.
2. People with a pre-existing, long-term disease affecting the shoulder, e.g., hemiplegia.
3. People who had prior neck dissection surgery on the affected side. People who had a previous neck dissection on the affected side (except sentinel lymph node biopsy requiring completion neck dissection)
4. People undergoing Lymph Node Biopsy or Sentinel Lymph Node Biopsy only.
5. Previous entry in the present trial.
6. Unable to adhere to trial processes.

Date of first enrolment
30/04/2025

Date of final enrolment
01/08/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Norwich
United Kingdom
NR4 7UY

Study participating centre
Oxford University Hospitals
Headington
Oxford

United Kingdom
OX3 9DU

Study participating centre
University Hospitals Dorset NHS Foundation Trust
Poole Hospital
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Royal Marsden Hospital
Royal Marsden Hospital
Fulham Road
London
United Kingdom
SW3 6JJ

Study participating centre
East Kent Hospitals University NHS Foundation Trust
Kent & Canterbury Hospital
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre
Mid and South Essex NHS Foundation Trust
Prittlewell Chase
Westcliff-on-sea
United Kingdom
SS0 0RY

Study participating centre
Somerset NHS Foundation Trust
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Sponsor information

Organisation
University of Warwick

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

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

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		02/10/2025	06/10/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes