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# Getting Recovery Right After Neck Dissection (GRRAND-F): Feasibility study to design a pragmatic randomised controlled trial

**Submission date**
23/09/2019

**Recruitment status**
No longer recruiting

**Registration date**
08/10/2019

**Overall study status**
Completed

**Last Edited**
07/06/2024

**Condition category**
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Head and neck cancer (HNC) affects over 9000 in the UK annually. People affected and surviving HNC in the UK are now younger and more active than previous generations. The treatment pathway for HNC is complex due to the varied anatomical sites of disease and the needs of the patient. With the advent of chemo-radiotherapy as a curative treatment, fewer patients require a neck dissection (ND). However, even with this approach, up to 20% of patients require an ND due to residual disease. After surgery ND is associated with both early and late complications, occurring in 50-100% of patients. Early complications can include shoulder pain and infection. Late complications include shoulder movement dysfunction, speech, swallowing and musculoskeletal problems such as cervical contracture and muscle wastage and can continue to be present over 5 years. Psychosocial complications are also highly prevalent after surgery, predominantly fatigue, anxiety, depression, sleep disturbance and social isolation. Shoulder dysfunction and psychosocial complications are strongly associated with reduced return to work, with up to 50% of patients ceasing working due to shoulder disability alone. Currently, there is no national standard best practice for the effective management of shoulder rehabilitation and associated complications following HNC. The researchers' study development work and feedback from Patient and Public (PPI) representatives have shown that physiotherapy practice varies across the UK. It suggests that rehabilitation in the form of physiotherapy is not routinely available to patients with HNC, either in an in-patient or outpatient settings. What is offered is not evidence-based, and when available, it is not focused and targets acute respiratory care, range of motion exercises for the neck and shoulder, and advice on positioning of the upper limb and shoulder girdle. Outpatient treatment is minimal, and most commonly reactive, driven by patient request. In addition to investigating the feasibility of an enhanced rehabilitation intervention following HNC ND, this study will also standardise usual care through a (control group) recovery framework and patient leaflet.

Who can participate?
Patients aged 18 and above being treated for HNC in whom an ND is part of their care

What does the study involve?
Participants are randomly allocated to one of two groups. Both groups receive inpatient physiotherapy and receive a booklet of advice and exercises on discharge. Those allocated to the intervention group also attend up to 6 sessions of outpatient physiotherapy over 6 months. Participants are asked to complete exercise diaries and outcome data at the start of the study and after 6 months and 12 months (if their appointment is before February 2021), clinical data are also collected at these times. Both groups will have optional consent for interviews. Of those who consent 15 participants are contacted to arrange face-to-face interviews to help increase our understanding of people's experiences of being involved in this study

What are the possible benefits and risks of participating?
The study will find out if it is possible to do a large trial investigating better physiotherapy treatments for people who have had an operation (neck dissection) for head and neck cancer treatment. The results of that study would then be able to tell physiotherapists if the GRRAND-F intervention is effective or not. 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. 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?
1. The Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS)
2. University of Oxford Botnar Research Centre

When is the study starting and how long is it expected to run for?
July 2018 to April 2022

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Scientific

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## Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
268845

### Protocol serial number
CPMS: 43309, IRAS: 268845

## Study information

### Scientific Title
Getting Recovery Right After Neck Dissection (GRRAND-F): Feasibility study to design a pragmatic randomised controlled trial

### Acronym
GRRAND-F

### Study objectives
Head and neck cancer (HNC) is becoming more common in the UK. The main treatments for HNC include surgery, radiotherapy, and chemotherapy. Treatment outcomes for HNC are improving, however, surgical side-effects can be significant, including swallowing problems, fatigue, anxiety, and shoulder problems. About half of people cannot return to work following their surgery and we do not know what the best way is to help people best recover.

This study will see if a rehabilitation treatment programme is acceptable for patients who have been discharged from hospital after surgery for HNC. The programme has been designed by physiotherapists and patients who have had HNC surgery.

### Ethics approval required

Old ethics approval format

## Ethics approval(s)
Approved 29/10/2019, Oxford B Research Ethics Committee (Whitefriars Level 3, Block B, Lewin's Mead, Bristol, BS1 2NT; +44 (0)207 104 8253; nrescommittee.southcentral-oxfordb@nhs.net), ref: 19/SC/0457

## Study design
Randomized; Interventional; Design type: Treatment, Education or Self-Management, Physical, Rehabilitation

## Primary study design
Interventional

## Study type(s)
Treatment

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

## Interventions
A mixed-methods feasibility study investigating the design of a randomised controlled trial to test the clinical and cost-effectiveness of an individualised, rehabilitation programme compared to usual care in patients undergoing a neck dissection for head and neck cancer. The study will be undertaken in secondary care head and neck cancer surgical centres across England to provide geographical and demographic variability to assess the feasibility study objectives.

Patients will be approached at their initial surgical consultation where the decision to undergo neck dissection will be made. Those who express an interest in the study will be approached a second time e.g. at their pre-operative assessment appointment (approximately two weeks prior to surgery) where they will be asked whether they wish to enrol onto the study. Consent will be sought at this appointment and baseline data collected. When the patient returns to the hospital for the operation, for those who have given consent, the post-operative surgical notes will be reviewed to verify eligibility. Consented participants who are still eligible will then be randomised.

As part of routine NHS care, all participants will be assessed by a physiotherapist within the first 24 hours postoperatively. All will receive routine ward-based physiotherapy including respiratory care, positioning and advice on walking and activities of daily living, in addition to advice on general exercises to start neck and shoulder exercises. This will be supplemented by a leaflet developed as part of this trial.

Those randomised to the control group will receive no further physiotherapy unless determined by the ward physiotherapist or a member of the surgical team at the time of discharge or thereafter. If they independently seek further physiotherapy, they will be asked to document when, where and for how long their physiotherapy lasted. Participants randomised to this group will receive no further out-patient (post-discharge from the hospital) physiotherapy but will be advised to continue with the exercises provided pre-hospital discharge, and to remain as generally physically active as possible. This mirrors routine physiotherapy care for this population.

Those randomised to the experimental group will receive the GRRAND intervention. This consists of usual care (as described above) PLUS an individualised physiotherapy intervention (up to six sessions) provided by a GRRAND-trained physiotherapist. The intervention will be individually tailored to each participant's clinical presentation and rehabilitation need. The components will include range of motion exercises, progressive resistance exercises, education and advice on positioning, oral health and pain management, exercise adherence, return to work and normal activities, scar management and education addressing fatigue, anxiety and sleep hygiene. The intervention consists of up to six sessions of physiotherapy, of 45 minutes each (except the first session which is 60 minutes). All sessions are to be completed within a maximum of 6 months post-hospital discharge.

Participants recruited will be enrolled for a minimum of six months post-randomisation to a maximum of 12 months post-randomisation depending on when the participant is recruited in the lifetime of the study. Only those randomised during the early part of the study will receive a 12-month questionnaire due to the availability of funding.

### Intervention Type
Other

### Primary outcome(s)
Recruitment and retention rates from study participants across sites, measured using overall study recruitment numbers, screening logs, consent forms and logs of data collection forms completed at 6 months and 12 months (for those participants who reach this timepoint within the study)

### Key secondary outcome(s))
Clinical outcome measures are primarily collected to calculate the sample size for the definitive trial. Outcome data to be collected at each of the data collection intervals (at baseline, 6 and 12 months unless stated otherwise) are listed below:

1. Shoulder pain and function measured using the well-validated Shoulder Pain and Disability Index (SPADI)
2. Pain measured using the SPADI 5-item Pain Sub-scale and using a numerical rating scale (0-10)
3. Pain medication details and usage – relating to head, neck and shoulder
4. Chemotherapy and radiotherapy treatment provision
5. Function measured using the SPADI 8-item Disability Sub-scale
6. Health-related quality of life measured using the EQ-5D-5L score and the EORTC questionnaires (C30 (core)) and H&N43 (head and neck specific)
7. Health resource use questionnaire (collection of health resources for computation of direct medical, direct nonmedical and indirect costs); additional out-of-pocket expenses; and work absence (number of sickness days)
8. Adverse events: such as prolonged delayed onset muscle soreness, swelling and wound irritation
9. Physical performance measures including shoulder and neck range of motion and grip strength measured at the 6-month and 12-month assessment by an appropriately trained and delegated member of the research team

The study will also conduct qualitative interviews of participants and physiotherapist to wider experiences, perceptions, feasibility and acceptability of the study design from a patient and physiotherapist perspective. This will also aim to determine the potential risks of intervention contamination.

### Completion date
30/04/2022

## Eligibility

### Key inclusion criteria
1. Men and women aged 18 years and above
2. Patients being treated for HNC in whom an ND is part of their care
3. Willing and able to provide informed consent
4. Able to understand written English
5. Willing to attend the physiotherapy outpatient department if randomised to the experimental intervention arm
6. Patients who remain eligible post-operatively when reviewed prior to randomisation

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment
36

### Key exclusion criteria
1. If treatment is palliative (expected survival six months or less)
2. Those with a pre-existing, long-term neurological disease affecting the shoulder e.g. hemiplegia

### Date of first enrolment
01/11/2019

### Date of final enrolment
31/10/2021

## Locations

### Countries of recruitment
United Kingdom

England

**Study participating centre**
**Oxford University Hospitals NHS Foundation Trust**
John Radcliffe Hospital
Headley Way
Headington
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United Kingdom
OX3 9DU

**Study participating centre**
**Norfolk and Norwich University Hospitals NHS Foundation Trust**
Colney Lane
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# Sponsor information

**Organisation**
Oxford University Hospitals NHS Foundation Trust

**ROR**
https://ror.org/03h2bh287

# Funder(s)

**Funder type**
Government

**Funder Name**
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-1217-20031

# 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

Data sharing statement to be made available at a later date

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 16/03/2023 | 04/04/2023 | Yes | No |
| Protocol article | | 21/06/2021 | 24/06/2021 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Other publications | Embedded qualitative interview study | 14/11/2022 | 15/11/2022 | Yes | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |