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Restoring Activity Post Surgery (RAPS)

Submission date 21/09/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/10/2010	**Overall study status** Completed	
Last Edited 24/01/2022	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-planned-exercise-programme-after-surgery-for-non-small-cell-lung-cancer-raps

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 6

Study information

Scientific Title

The effect of post operative physical training on activity after curative surgery for Non Small Cell Lung Cancer: Restoring Activity Post Surgery (RAPS)

Acronym
RAPS

Study objectives
Does structured, physiotherapy led cycle ergometry strength training and a home walking programme, provided after curative surgery for lung cancer, result in improved activity at 4 weeks post discharge compared with usual care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
East London Research Ethics Committee 1 (previously: East London & The City Research Ethics Committee Alpha) approved on the 12th of August 2010 (ref: 10/H0704/36)

Study design
Randomised controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Non Small Cell Lung Cancer NSCLC)

Interventions
Patients will be randomised to:
1. Intervention Group: Training programme
1.1. Structured, physiotherapy-led cycle ergometry strength training programme once a day during inpatient stay
Symptom limited constant load cycle ergometry protocol: Following patient familiarisation with the ergometer, correct seat adjustment (recording seat height/position), patient completes warm-up phase during 0-2 minutes consisting of unloaded pedalling at 50-60rpm. Intensity of cycling is increased steadily during the 3rd minute to achieve max 60-90% Heart Rate Reserve (Target HR range = ([HRmax HRrest] x percent intensity) + HRrest but also taking account of the

following correction factor: 12/25% reduction in pre-op max load for Lobectomy /Pneumonectomy (Pelletier et al., 1990. Thorax 45(7): 497; 502). Patients will be advised to exercise at an intensity relating to Borg CR10 Breathlessness Scale (BBS) 3-4 and Borg Rating of Perceived Exertion (RPE) 13-15, pedalling rate should be held between 50-60 rpm. Patient should aim to complete >5 minutes Day 1 Post-Op, increasing to maximal duration 30 minutes at Day 5. Warm-down of at least 2 minutes unloaded pedalling until observed HR/SpO2% return towards resting values (~10 bpm of rest).
1.2. Home walking programme
Daily aiming to get patients to achieve 30 mins walking per day so self-managed with bi-weekly phone calls from research tea

2. Control Group: Usual care

Follow up for all arms is 4 weeks post discharge.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Physical activity monitoring (time spent in moderate intensity activity measured using Actiwatch). The Actiwatch spectrum (Phillips Respironics) is worn like a wristwatch. It records the amplitude of physical activity. Data are downloaded by the researchers and the patient needs to do nothing other than wear it. Actiwatch data is collated daily for a period of three days pre-operatively, during in-patient stay to a maximum of 5 days and 3 days before the 4 week follow up.

Secondary outcome measures
1. Quadriceps muscle strength measured as maximum voluntary contraction force
2. Exercise tolerance using Incremental Shuttle Walk Test
3. Quality of Life using EORTC and SF36 questionnaires
4. Length of hospital stay
5. Post-operative complications

Outcomes are measured pre-operatively, 5 days post-operatively (or sooner if discharge is earlier then on day of discharge), and 4 weeks post-operatively.

Overall study start date
01/09/2010

Completion date
30/04/2012

Eligibility

Key inclusion criteria
Patients (either sex) with lung cancer referred for curative lung resection (lobectomy and or pneumonectomy) via open thoracotomy or Video Assisted Thoracotomy (VATS).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
125

Key exclusion criteria
1. Patients who have open and closed thoracotomy performed but no other surgical procedure
2. Admission greater than 48 hours to Intensive Care Unit post surgery

Date of first enrolment
01/09/2010

Date of final enrolment
30/04/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Pulmonary Rehabilitation
London
United Kingdom
SE22 8PT

Sponsor information

Organisation
Kings College NHS Foundation Trust (UK)

Sponsor details
Jennie Lee House
34 Love Walk
Denmark Hill
London

England
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Charity

Funder Name
British Lung Foundation (UK) - (ref: CAN09/1)

Alternative Name(s)
BLF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	01/06/2014		Yes	No
Plain English results			24/01/2022	No	Yes