

Restoring Activity Post Surgery (RAPS)

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| Submission date 21/09/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 27/10/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 24/01/2022 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

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

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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 = $[(HR_{max} - HR_{rest}) \times \text{percent intensity}] + HR_{rest}$ 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(s)

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.

Key secondary outcome(s)

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 than on day of discharge), and 4 weeks post-operatively.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre**Pulmonary Rehabilitation**

London

United Kingdom

SE22 8PT

Sponsor information

Organisation

Kings College NHS Foundation Trust (UK)

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

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 |