ISRCTN92666109 https://doi.org/10.1186/ISRCTN92666109

Integrated rehabilitation for thoracic cancer

Submission date
29/01/2018

Recruitment status
No longer recruiting

Registration date
30/01/2018

Overall study status
Completed

Last Edited
12/08/2022

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
At any one time, over 65,000 people are alive in the UK having been given a lung cancer diagnosis. The condition and its medical treatment (with chemotherapy, radiotherapy and surgery) cause many symptoms that affect day-to-day life. These include breathlessness, weakness and tiredness or fatigue. Rehabilitation treatments can help to relieve these symptoms and can help people to stay active and independent whilst living with lung cancer. Most research studies to date have offered rehabilitation in the form of supervised exercise programmes. These involve vigorous physical training, over several months, and often take place in a hospital setting, so require a lot of commitment from the person with cancer. Many people do not feel able to take part in these intensive programmes and miss out on rehabilitation. The aim of this project is test a different form of rehabilitation service, which may help more people to access and benefit from rehabilitation.

Who can participate?
Adults who have been recently diagnosed with lung cancer or pleural mesothelioma.

What does the study involve?
Participants are offered the rehabilitation service close to the time when they are diagnosed to help them prepare for medical treatments and stay active. This is delivered by a specialist physiotherapist and is short-term so the person can benefit from advice and education quickly and does not have to sign up to a long programme. It is delivered alongside the care other health professions provide for the person with cancer, such as their cancer doctor or nurse. People recently diagnosed with lung cancer are randomly allocated to receive the rehabilitation service or usual care. People allocated to receive the service have three contacts with the physiotherapist. These are discuss symptom and problems that are limiting their daily living, to learn about ways to self-manage these, and to develop an action plan to encourage good health behaviours, such as staying active by pacing daily tasks. We Markers of how well the research study went, including how many people took part, their experiences of the research and the extent to which people receive the care they were allocated to are measured. Symptom distress, physical activity levels, functional ability and quality of life before and after the service (or usual care) are assessed.

What are the possible benefits and risks of participating?
The trial is designed to understand if short-term rehabilitation can benefit people with lung

cancer or mesothelioma. We don't know if it will benefit people but the information we get from this trial will help improve the future treatment of people with lung cancer or mesothelioma. It is a very low risk trial. Rehabilitation is tolerated by people with a wide range of health conditions. The rehabilitation will be tailored to each person's needs and capability. Some people may benefit from the rehabilitation but it is possible other people will not benefit from rehabilitation.

Where is the study run from?
Kings College London (UK)

When is the study starting and how long is it expected to run for?
May 2015 to May 2019

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

Who is the main contact?
Jo Bayly (Scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
35673

Study information

Scientific Title

Short term integrated rehabilitation for people with thoracic cancer: A feasibility trial

Study objectives
This is a study to find out if people who have recently been diagnosed with lung cancer or mesothelioma are willing to participate in a short rehabilitation programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London South East Research Ethics Committee, 23/11/2017, ref: 17/LO/1871

Study design
Randomised; Interventional; Design type: Treatment, Complex Intervention, Rehabilitation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Cancer, Primary sub-specialty: Palliative and supportive care; UKCRC code/ Disease: Cancer/ Malignant neoplasms of respiratory and intrathoracic organs

Interventions
This study is testing the feasibility of a short term rehabilitation service for patients who have been diagnosed with either lung cancer or pleural mesothelioma within the last 8 weeks.

Participants are randomly allocated to one of two groups.

One group receives standard care as usual.

One group receives standard care plus a short term rehabilitation service. This involves up to three sessions with a physiotherapist in either the hospital or home setting.

Key components of the service include:
1. Checking patient's understanding and beliefs about their illness, their concerns and treatment goals
2. Screening how well they are functioning in daily life
3. Information and strategies to support self-management
4. Help for patient and family to anticipate and manage future situations, e.g. deterioration
5. A rehabilitation action plan, integrated follow up and onward referral to existing services

Intervention Type
Behavioural

Primary outcome(s)
The primary aim of this study is to establish the feasibility of a future definitive trial; as such it's aims are:
1. To inform the recruitment, sample size and timeline of a future fully-powered trial, by

establishing the number of participants identified, approached, consented, randomised and completed over the trial period and the rate of recruitment per month.
2. To inform future trial procedures by establishing the acceptability and experience of the trial processes to participants; including randomisation, the proportion of randomised patients remaining on trial for 30 and 60 days, the number of physiotherapy contacts received and reasons for drop out.
3. To refine future trial procedures by establishing response and completion rates for each trial outcome at baseline, 30 and 60 days, summarised overall and by trial arm.
4. To further assess the acceptability of the trial procedures by evaluating treatment fidelity and contamination using number of planned contacts per participant, number of patients seen with carer and mode of contact, the proportion of patients with a rehabilitation plan.
5. To further assess the acceptability of the intervention by evaluating the uptake of discreet components: i. self-management of symptoms, ii. maintain physical activity and fitness, iii. maintain task performance and participation in activities, iv. onward referral to other services by treatment arm.

Key secondary outcome(s))
The self-reported outcome measures that will be evaluated within this feasibility study are as follows:
1. Symptom levels, measured using the Integrated Palliative Care Outcome Scale (iPOS) completed at baseline and 30 and 60 days post baseline.
2. Physical activity levels, measured using the Physical Activity Scale for the Elderly (PASE).
3. Confidence and self-efficacy to manage the impact of illness and treatment, measured using the Self-efficacy measure for chronic disease (SEMCD).
4. Health-Related Quality of life, measured using the Functional Assessment of Cancer Therapy-Lung (FACT-L) and the FACT-L Trial Outcome Index (FACT-L TOI) and the EuroQol 5-Dimension 5 Level (EQ-5D-5L).
5. Participant's recent health service use will be measured using the Client Service Receipt Inventory (CSRI).
6. Participants experience of receiving the trial rehabilitation intervention, measured using the Functional Assessment of Chronic Illness Therapy - Treatment Satisfaction – Patient Satisfaction (FACIT-TS=PS).
7. Experience of participating in the trial will be evaluated in both arms using questions from the National Institute of Health Research Clinical Research Network Coordinating Centre Patient Research Experience Questionnaire.

Completion date
31/05/2019

Eligibility

Key inclusion criteria
1. Age >18 years
2. Clinical or histological diagnosis of NSCLC, SCLC or MPM, within the last 8 weeks
3. ECOG performance status 0-3
4. Ability to respond to questions in written English – or availability of interpreters to enable this

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
54

Key exclusion criteria
1. Co-existing progressive neurological condition (e.g. multiple sclerosis, motor neurone disease)
2. ECOG performance status 4(due to association with short survival)
3. Inability to complete patient questionnaires due to cognitive impairment, or language difficulties and lack of interpreters
4. Patients currently receiving specialist rehabilitation, or planned to receive within the next month
5. Receiving palliative care with expectation of death within 1 month

Date of first enrolment
01/02/2018

Date of final enrolment
07/01/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King’s College Hospital (lead centre)
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Princess Royal University Hospital
Farnborough Common
Kent

United Kingdom
BR6 8ND

Study participating centre
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name

National Institute for Health 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
Current IPD sharing statement as of 25/02/2020:
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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Previous IPD sharing statement:
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?
Results article	results	01/02/2020	25/02/2020	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2	27/11/2017	12/08/2022	No	No