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The Prehabilitation Radiotherapy Exercise, smoking Habit cessation and Balanced diet Study (PREHABS) protocol to explore the feasibility of embedding behavioural modifications into the clinical pathway for patients undergoing radical radiotherapy for lung cancer

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ABSTRACT

Patients with curable non-surgical lung cancer are often current smokers, have co-existing medical comorbidities and are treated with curative radiotherapy. To maximise the benefits of modern radiotherapy, there is an urgent need to optimise the patient's health to improve survival and quality of life.

Methods and analysis The Yorkshire Cancer Research-funded Prehabilitation Radiotherapy Exercise, smoking Habit cessation and Balanced diet Study (PREHABS) (L426) is a single-centre prospective feasibility study to assess embedding behavioural changes into the radical radiotherapy pathway of patients with lung cancer. Feasibility will be assessed by measuring acceptability, demand and implementation. The duration of the study is 24 months. PREHABS has two workstreams: the intervention study and the theory of change (ToC) study. *Intervention study*: PREHABS will commence at the R-IDEAL phase 2 trial (exploratory) based on existing evidence and includes support for smoking cessation, increasing activity and dietary well-being. Patients undergoing radical radiotherapy for lung cancer will be recruited from the oncology department at Leeds Teaching Hospitals NHS Trust (LTHT). *ToC study*: to maximise the acceptability and adherence to the PREHABS, we will use a ToC approach to qualitatively explore the key barriers and enablers of implementing a tailored programme of 'prehabilitation'. The PREHABS ToC study participants will be recruited from patients with lung cancer undergoing radical radiotherapy and staff from the LTHT oncology department.

Analysis The primary endpoint analysis will report the number of participants and adherence to the study interventions. Secondary endpoints include continued engagement with study interventions post-treatment. The analysis will focus on descriptive statistics. Thematic analysis of the qualitative data from the ToC study will identify consensus on intervention optimisation and delivery.

Ethics and dissemination On 12 May 2021, the Cambridge East Ethics Committee granted ethical approval (21/EE/0048). The study is registered in the National Institute for Health and Care Research (NIHR) portfolio. The results will be disseminated through publication in peer-reviewed scientific journals and presented at conferences.

Trial registration number NIHR portfolio 48420.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Using the clinical treatment location and clinical staff for the delivery of the research interventions provides an efficient method of maximising the opportunity and equity for patients to engage without the need for additional visits.
⇒ The use of patient involvement from inception to dissemination in this project provides a mechanism to include the views of patients at all stages to develop an intervention package that is acceptable for patients.
⇒ Using the theory of change methodology allows for an iterative method to amend the delivery of the interventions to maximise patient engagement and adherence.
⇒ As a single-centre feasibility study, there will be a need to explore the results of the Prehabilitation Radiotherapy Exercise, smoking Habit cessation and Balanced diet Study in a larger patient cohort and at multiple sites.

INTRODUCTION

Lung cancer

Lung cancer is a common cancer in the UK with an incidence of 83 per 100 000.[1] The incidence of lung cancer is predicted to increase over the next 10–20 years (about 15 000 more cases per year in 2035); however, survival rates will also increase, resulting in more people living with possible consequences of treatment.[2]

Curable lung cancer can be treated with surgery and/or radiotherapy with systemic therapies for suitable patients. Many patients with lung cancer are elderly, current smokers and have co-existing medical comorbidities[3]; 54% present with three or more,[4] which precludes them from surgery. Advances in radiotherapy increase the chance that patients survive their lung cancer but die due to other existing medical conditions.[5]

Prehabilitation

The concept of prehabilitation is not new.[6 7] The use of prehabilitation programmes have been routinely used in orthopaedic surgery, resulting in decreased surgical complication rates, shorter hospital stays and a quicker return to normal activity.[8–10]

There is a growing body of research studying prehabilitation intervention in oncology patients, primarily those undergoing surgical resection[11–14] with an emphasis on abdominal and pelvic tumours.[13–16] Prehabilitation interventions include a range of aerobic and non-aerobic exercises, support for stopping smoking, pulmonary exercises and an improved diet.[17–22] The studies found that the pretreatment intervention improved the outcome and the quality of life (QoL) for the patient postprocedure.

The use of prehabilitation in patients undergoing radiotherapy is limited.[20 23 24] Unlike surgery, curative radiotherapy is not a 'one-off' treatment, with patients attending up to 33 daily treatment sessions. This daily attendance provides multiple opportunities to engage with patients and provide them with support to modify their behaviours.

Every contact counts

In 2016, Health Education England published a statement paper advocating the use of routine clinical appointments with patients to promote providing support to patients in making positive behavioural changes: making every contact count (MECC).[25] The aim of MECC is to provide patients with information that may improve their physical and mental well-being.

The radiotherapy pathway provides multiple opportunities to practice MECC. Patients attend the radiotherapy department up to 33 times, depending on the radiotherapy treatment regimen. Therapeutic radiographers are healthcare professionals who deliver radiotherapy treatments to patients. Their daily interaction with patients provides an opportunity to advise and support patients in modifying their behaviours with regard to their lifestyle choices.[25] Following appropriate training, the scope of practice of radiographers can be increased to provide exercise and smoking cessation advice.[26]

Rationale

To maximise the benefits of modern radiotherapy, there is an urgent need to optimise the patients' health before, during and after radiotherapy. Increasing the mental and physical fitness of patients with lung cancer will result in a decrease in treatment side effects, an improvement in their well-being and potentially the survival of these patients (figure 1).

Making the most of the multiple interactions with patients undergoing radiotherapy treatments and upskilling therapeutic radiographers provides an opportunity to provide a bespoke support package to help patients modify their lifestyle behaviours.

Delivering support and information at the point of delivery of standard treatment may improve the QoL and treatment outcomes and allow for equitable provision of support, regardless of personal status.

Aim

The aim of the Prehabilitation Radiotherapy Exercise, smoking Habit cessation and Balanced diet Study (PREHABS) is to assess the feasibility of implementing a rehabilitation programme through the clinical pathway of patients undergoing radiotherapy for curative lung cancer.

Dates of the study

The PREHABS opened for recruitment on 1 September 2021. Follow-up of recruited patients will cease on 31 October 2023.

Objectives

The primary objectives of this study will be measured to assess feasibility, which will help inform the next stage of this programme of work[27]:

1. Acceptability.
2. Demand.
3. Implementation.
4. Practicality.
5. Adaptation.
6. Integration.
7. Expansion.

In addition, a set of secondary objectives will also be measured:

1. Compliance with a bespoke exercise programme.
2. Smoking cessation rates.
3. Nutritional outcome measures.
4. QoL.
5. Hospital admission rates during and after radiotherapy (number of hospital interactions).
6. Health economic assessment.

Study endpoints are described in tables 1 and 2.

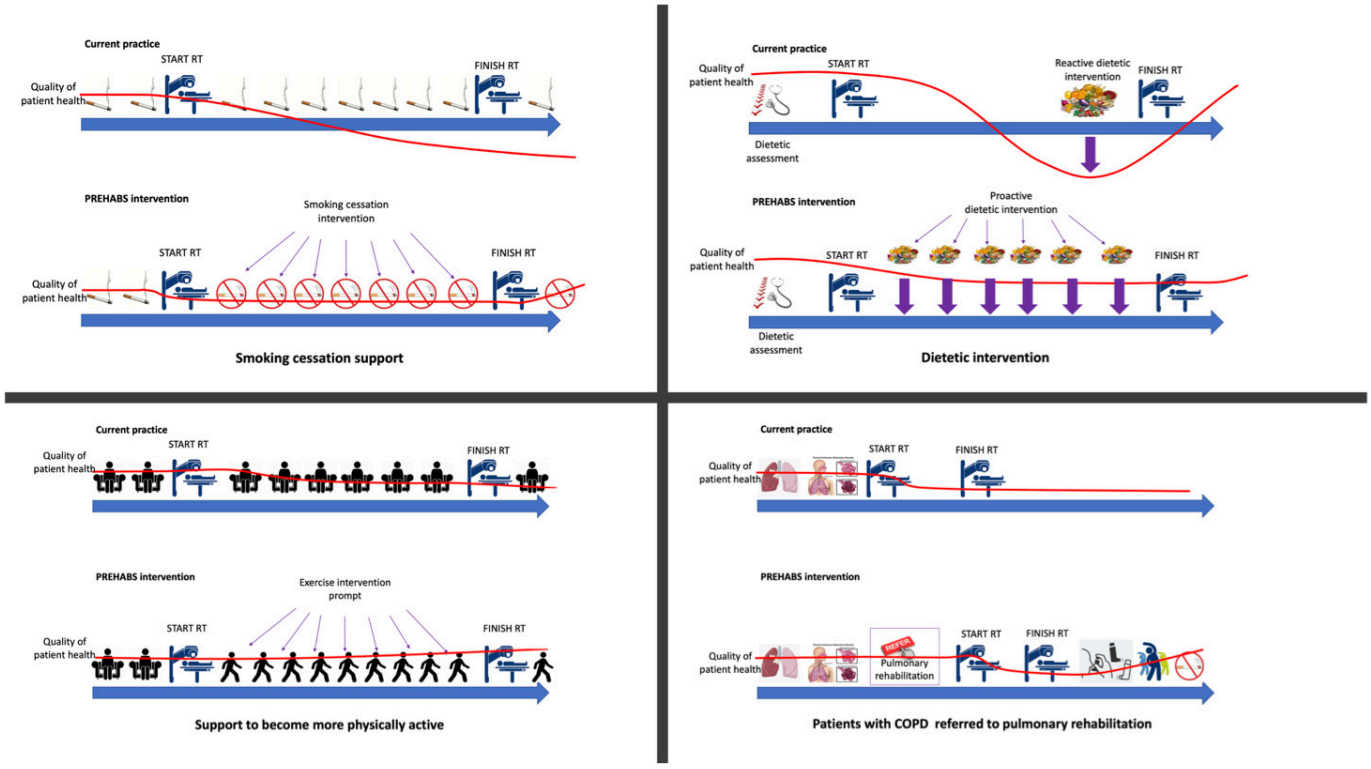

Figure 1 Potential benefits of implementing Prehabilitation Radiotherapy Exercise, smoking Habit cessation and Balanced diet Study within the patient pathway of patients undergoing curative radiotherapy for lung cancer.

METHODS

PREHABS is a single-centre prospective feasibility study. The study will assess the feasibility of embedding lifestyle and behavioural changes into the clinical pathway of patients with lung cancer undergoing radical radiotherapy (figure 2). The methodology of the study has been selected in line with Medical Research Council guidance for designing complex interventional studies.[28]

The PREHABS will be conducted using two workstreams:

1. The main PREHABS intervention study.
2. The Theory of Change (ToC) study: a qualitative substudy to allow for intervention optimisation to take place during the study.

The duration of the study is 24 months.

Recruitment of participants

Interventional workstream

Patients with lung cancer (n=90) undergoing radical radiotherapy will be recruited from the Leeds Teaching Hospital NHS Trust (LTHT) oncology lung cancer clinics.

ToC workstream

Patients with current and past lung cancer (n=20) and staff (n=10) working in the radiotherapy department will be eligible to be included in the ToC workstream.

Workstream 1: intervention study

The intervention study will assess the feasibility of embedding lifestyle modifications into the clinical pathway of patients undergoing radical radiotherapy for lung cancer.

PREHABS fits the R-IDEAL methodology model.[29 30] Based on the validated methodology used in surgery,[30 31] R-IDEAL follows a five-step process:

- Preclinical: theory.
- Phase 1: modelling.
- Phase 2: exploratory trial.
- Phase 3: definitive randomised control trial.
- Phase 4: long-term implementation.

PREHABS will commence at the R-IDEAL phase 2 trial (exploratory) as the theoretical components (preclinical phase) and modelling (of the interventions) of the study have already been carried out in vivo.[18 21 32–35]

The interventions selected for the PREHABS have all been proven to have a benefit to patient well-being.

Refinement of the PREHABS 'menu' of interventions will occur as the study progresses. We will be using our patients to help inform and design the programme of prehabilitation so that it is acceptable for our patient cohort (ToC).

The interventions included in the PREHABS are as follows.

Support to become more physically active

A bespoke PREHABS exercise regime will be developed from previously validated exercise programmes.

Smoking cessation support

Patients will be offered weekly intensive smoking cessation support in the radiotherapy department. by delivering a

Table 1 Primary endpoints of the Prehabilitation Radiotherapy Exercise, smoking Habit cessation and Balanced diet Study

Primary endpoints	Acceptability ► Reasons expressed by patients for declining or accepting recruitment, as assessed by the qualitative substudy. Demand ► Number of patients screened for eligibility. ► Number and proportion of patients eligible out of those screened and reasons for ineligibility. ► Number and proportion of patients who consent out of those eligible and reasons for non-consent. ► Number of patients consenting per month. Implementation ► Number of patients taking up referred interventions. ► Exercise. ► Smoking. ► Diet. ► Length of time between referral for pulmonary rehabilitation and appointment. ► Uptake and completion rate for pulmonary rehabilitation. Intervention compliance and reasons for non-compliance. ► Number, proportion and timing of withdrawals and reasons for withdrawals out of those registered. ► Number and proportion of participants lost-to-follow-up out of those registered. ► Number and proportion of participants with self-reported questionnaire data at each time point out of those registered.

Table 2 Secondary endpoints of the Prehabilitation Radiotherapy Exercise, smoking Habit cessation and Balanced diet Study

Secondary endpoints	Exercise ► Godin Leisure-Time Exercise questionnaire score. ► Assessment of Sedentary Behaviour questionnaire score. ► Exercise Barriers and Benefits questionnaire score. Smoking cessation metrics ► Number of participants who stop smoking. ► Self-reported continuous smoking cessation at 6-week, 16-week, 26-week and 52-week postradiotherapy. ► Carbon monoxide validated cessation at 6-week, 16-week, 26-week and 52-week postradiotherapy. Dietetic measurements ► Body weight. ► Body mass index measurements. ► Percentage body weight change. ► Hand grip. ► Mid-upper arm circumference. ► Incidence and duration (days) of enteral feeding pretreatment and post-treatment. Quality of life ► European Organisation for Research and treatment of Cancer (EORTC QLQ-C30 and Warwick Edinburgh Mental Well-Being Scale, EuroQol (EQ-5D-L scores). ► Number of hospital interactions. Health economic assessment Safety

12-week course of smoking cessation, including dispensing nicotine replacement therapy (NRT).

Dietetic support

Personalised dietary advice will be given to the patient at the commencement of the prehabilitation programme by a specialised dietician, and review will continue weekly during treatment.

Pulmonary rehabilitation

Patients with a diagnosis of chronic obstructed pulmonary disease (COPD) who meet the National Institute of Health and Care Excellence (NICE) and British Thoracic Society (BTS) criteria will be signposted to the existing standard of care community pulmonary rehabilitation programmes.[35]

Inclusion and exclusion criteria

Patients meeting the inclusion criteria will be invited to enrol in the PREHABS (figure 3).

Inclusion criteria

1. Undergoing radical radiotherapy for lung cancer.
2. Have radiotherapy follow-up care at LTHT.
3. Able to consent.
4. Over the age of 18.
5. Patients without a history of eating disorders.

Exclusion criteria

1. Not undergoing radical radiotherapy for lung cancer.
2. Do not have radiotherapy follow-up care at LTHT.
3. Unable to consent.
4. Under the age of 18.
5. Patients with a history of eating disorders.
6. Patients who are participating in another research study, which would compromise either study.

A verbal explanation of the trial and Patient Information Sheet will be provided by authorised trial staff for the patient to consider. Patients who are interested in participating will then be formally assessed for eligibility and invited to provide informed, written consent.

Consented patients will be allocated to the study intervention arm(s) depending on their eligibility (eg, whether a patient smokes or not) and the choice of the patient to engage with the intervention(s) (opt-in).

Baseline assessments will be completed before the delivery of the interventions. The PREHABS lifestyle

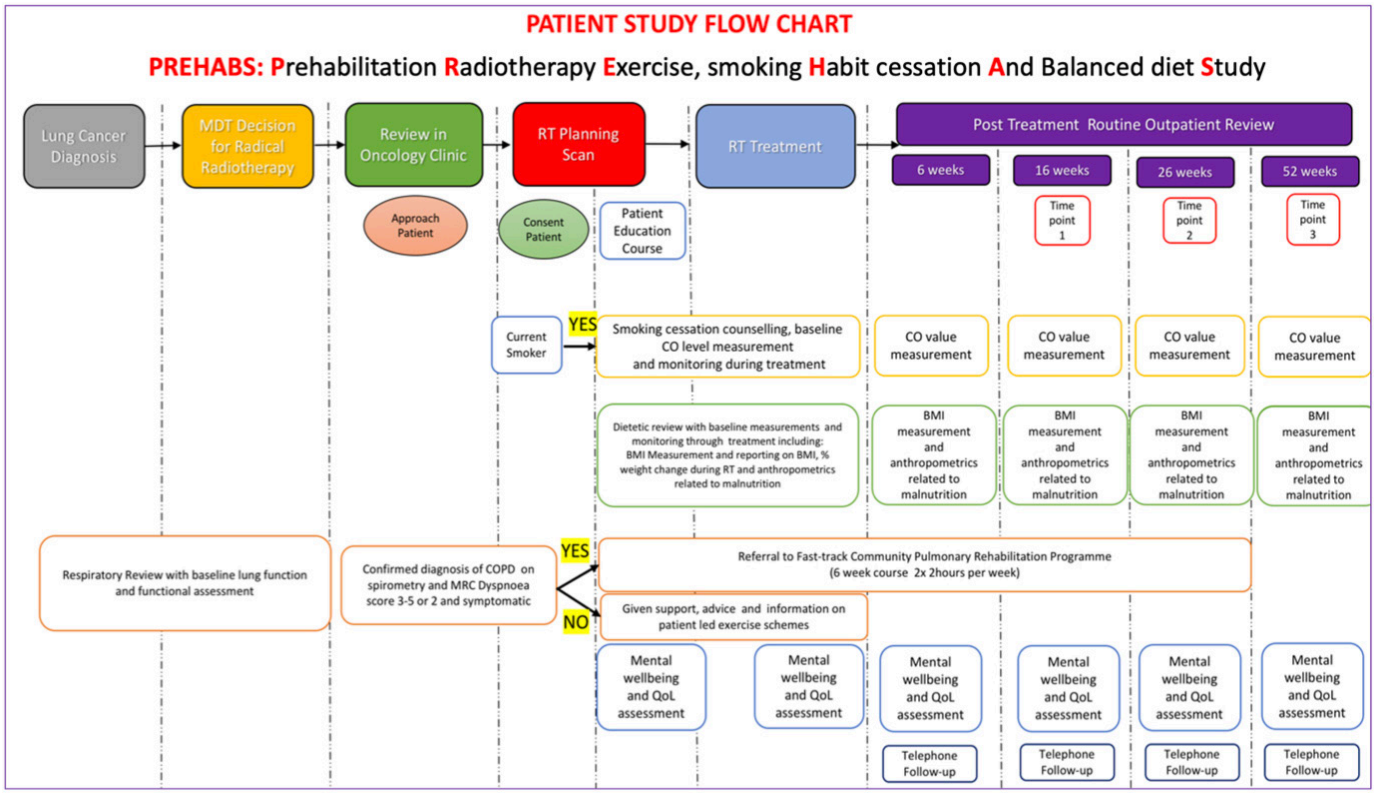

Figure 2 Schematic depicting the overview of the Prehabilitation Radiotherapy Exercise, smoking Habit cessation and Balanced diet Study.

interventions will be assessed at predetermined points within the patient's radiotherapy pathway (dependent on the course of radiotherapy prescribed).

Interventions

General physical fitness

A bespoke PREHABS exercise regime will be developed from previously validated exercise programmes and will be guided by self-determination theory. It will be supplemented by Macmillan's 'Move More' resources and Yorkshire Cancer Research's Active Beyond Cancer programme and be prescribed for each PREHABS participant.

A 20-min motivational interview (MI), based on the UK's NICE's guidance on promoting physical activity in primary care, will be performed. 'MIs' are a patient-centred counselling style that enhances an individual's motivation to change and will be used to:

1. Assess the patient's readiness to change and motivation to adhere to the intervention.
2. Determine the patient's current physical activity levels, guided by the Physical Activity Vital Sign (PAVS).
3. Co-design a tailored intervention based on patients' preferences and needs.
4. Explore the patient's interest in the use of intervention resource materials.
5. Encourage patients to plan how they will incorporate the physical activity intervention into their daily lives.
6. Provide a written physical activity prescription that is individually tailored.

Metrics

Baseline (week 0)

Self-report questionnaires: the Physical Activity Questionnaire (Godin Leisure-time Exercise questionnaire), the Assessment of Sedentary Behaviour (SIT-Q-7d) and the Exercise Benefits and Barriers Scale (EBBS) will be completed.

Week 6 (mid-intervention)

- Follow-up telephone interview (administer the PAVS).
- Self-report questionnaires: the Godin Leisure-time Exercise questionnaire, the SIT-Q-7d questionnaire and the Exercise Benefits and Barriers questionnaire.

Week 12 (postintervention)

- Follow-up telephone interview (administer the PAVS).
- Self-report questionnaires: the Godin Leisure-time Exercise questionnaire, the SIT-Q-7d questionnaire and the Exercise Benefits and Barriers questionnaire.

Months 6 and 12 (postradiotherapy)

- Follow-up telephone interview.
- Self-report questionnaires: the Godin Leisure-time Exercise questionnaire, the SIT-Q-7d questionnaire and the Exercise Benefits and Barriers questionnaire.

Smoking cessation

Patients will be offered weekly intensive smoking cessation support in the radiotherapy department with a trained smoking cessation counsellor. The PREHABS will

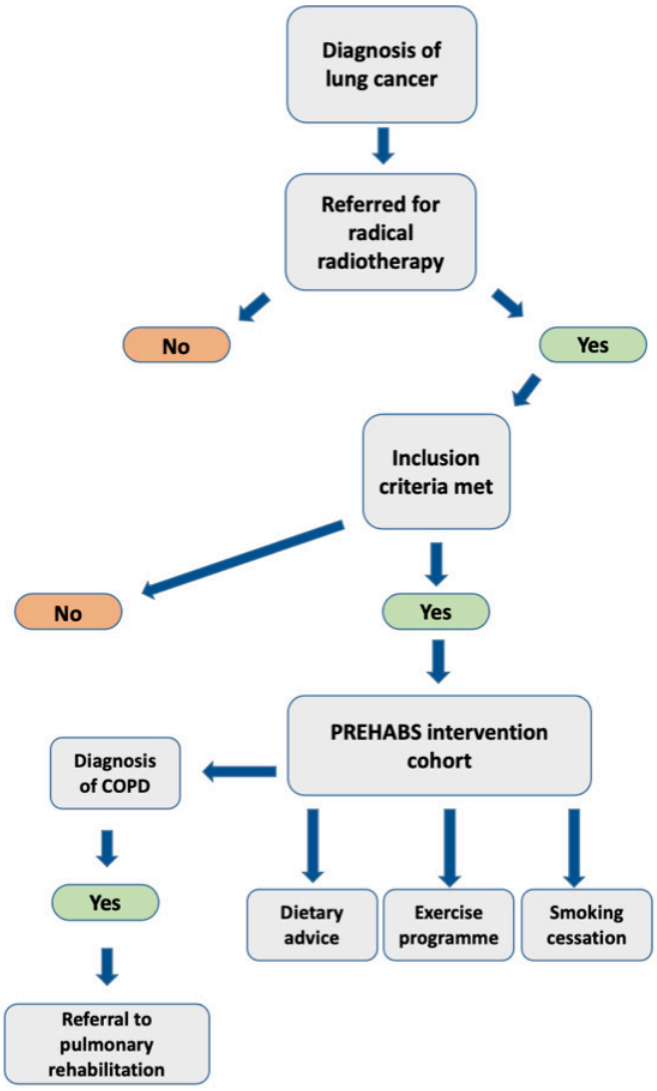

Figure 3 PREHABS algorithm. COPD, chronic obstructed pulmonary disease; PREHABS, Prehabilitation Radiotherapy Exercise, smoking Habit cessation and Balanced diet Study.

follow good practices that have been established in the Yorkshire Enhanced Stop Smoking study (Clinicaltrials.gov number NCT03750110). The aim will be to deliver a 12-week course on smoking cessation and provide the dispensing of NRT products every 2 weeks.

Research allied health professionals (AHPs) will be upskilled to provide in-house smoking cessation counselling (National Centre for Smoking Cessation and Training Standards). Nicotine replacement medication and e-cigarettes will be dispensed by the AHPs according to a standard operating protocol.

We will seek to obtain carbon monoxide (CO) testing on a weekly basis at their radiotherapy appointments and at follow-up clinic appointments postradiotherapy at approximately 6, 16, 26 and 52 weeks.

All patients will be asked to complete a smoking habit questionnaire, which identifies the 'want' of patients to quit smoking, the amount of tobacco smoked and the cost of tobacco products.

Metric

Reduced smoking rates, CO readings, number of NRTs dispensed and smoking habit questionnaires.

Diet

Personalised dietary advice will be given to the patient at the commencement of the prehabilitation programme by a specialised dietician. Weekly dietician review will continue during treatment, and the patients' body weight, body mass index (BMI) and percentage body weight change will be recorded before, during (weekly) and after the radiotherapy treatment in routine outpatient appointments (6-week, 16-week, 26-week and 52-week clinic appointments). In addition, anthropometrics related to malnutrition will be measured.

Patients will be asked to complete the provided PREHABS food diary, detailing their dietary and fluid intake and their compliance with prescribed nutritional supplement drinks and enteral feeds.

Metric

Body weight, BMI measurements, percentage body weight change, hand grip, mid-upper arm circumference and incidence and duration (days) of enteral feeding pretreatment and post-treatment (6-week, 16-week, 26-week and 52-week post-treatment).

Attendance of pulmonary rehabilitation classes

Patients with a diagnosis of COPD who meet the NICE and BTS criteria for pulmonary rehabilitation will be signposted to the existing standard of care community pulmonary rehabilitation programmes.

Metric

How many patients meet the referral criteria, the length of time from referral to commencing the rehabilitation programme, the acceptance rate of referrals to patients and the completion rates of the rehabilitation programme.

ToC embedded qualitative substudy

The PREHABS will be an iterative process, providing the ability to modify the study interventions based on the feedback of the patients and research team. The ToC[36] approach will be used to qualitatively explore the key barriers and enablers of implementing a tailored programme of 'prehabilitation' for patients with lung cancer (figure 4).

Within the context of the PREHABS, the ToC will:

1. Refine our ToC framework for a tailored prehabilitation programme with key stakeholders.
2. Explore why patients decline participation in a tailored prehabilitation programme.
3. Explore the barriers and enablers of adopting lifestyle adaptations as experienced by patients participating in the tailored prehabilitation programme.
4. Explore the experiences of key stakeholders in implementing a tailored prehabilitation programme in this context.

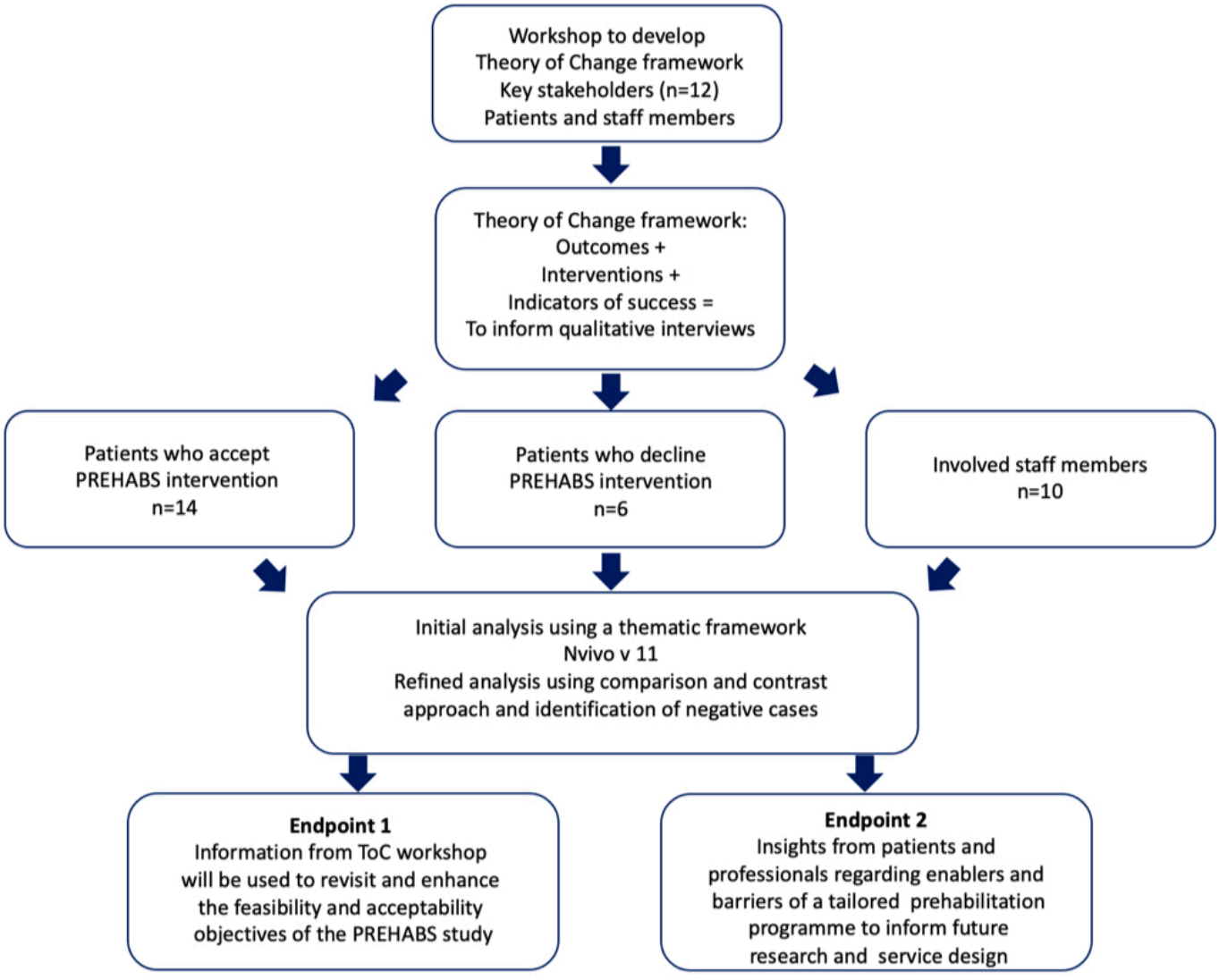

Figure 4 Theory of Change study algorithm. PREHABS, Prehabilitation Radiotherapy Exercise, smoking Habit cessation and Balanced diet Study; ToC, theory of change.

Design

The ToC study is a qualitative inductive study with key objectives.

1. Deliver a workshop to develop a theory of change framework for a tailored prehabilitation programme with key stakeholders prior to the start of the study.
2. Conduct qualitative interviews to explore why patients decline participation in a tailored prehabilitation programme.
3. Conduct qualitative interviews to explore the barriers and enablers of adopting lifestyle adaptations as experienced by patients participating in the tailored prehabilitation programme.
4. Conduct qualitative interviews with key stakeholders to explore their experiences of implementing a tailored prehabilitation programme in this context.

A workshop for approximately 10–12 key stakeholders to develop the ToC programme for the PREHABS will be held prior to the commencement of the PREHABS. The stakeholders will be identified by the trial management committee as being key to the strategy for this project or its implementation.

The stages of this work will be:

1. Construct a ToC map, including:
   1. Identify the short-term, medium-term and long-term outcomes and benefits of the 'prehabilitation programme'.
   2. Map out key interventions and key resources needed for delivery.
   3. Identify assumptions and rationales about why and how change might occur in the programme.
2. Define indicators of success, including:
   1. Who will experience the impact?
   2. Share the ToC with a broader group of stakeholders to gain consensus across the health economy about how this programme should work in practice.
   3. Use the ToC to review the acceptability and feasibility objectives of the prehabilitation programme and to enable monitoring and evaluation throughout the project.

4. Use information from the ToC to guide discussion in interviews with patients and professionals.

Interviews with patients

Patient selection

Patients who meet the inclusion criteria will be invited to take part in an interview. The patients will be approached by a member of their clinical team, who will briefly describe the qualitative study and ask the patient for verbal consent to be contacted by the qualitative researchers to discuss the study in more detail.

Patient sample

We will use convenience sampling to recruit our patients, with demographic criteria being considered so as to be representative of the patient group.

Patient inclusion criteria

Adult patients who have been diagnosed with lung cancer and have been or are being treated with radical radiotherapy at LTHT. Patients who either (1) choose not to participate in the PREHABS intervention or (2) agree to participate in the tailored PREHABS intervention will be included.

Patient exclusion criteria

Patients who have not been treated at LTHT for lung cancer with radical radiotherapy.

Patient interviews

In-depth qualitative interviews will be conducted using a predesigned topic guide with up to 20 patients (six patients who decline to take part and 14 patients who participate in the PREHABS). This will be subject to data saturation. Interviews will take about an hour and will be audio-recorded on an encrypted laptop or dictaphone.

Patient topic guide

A semistructured topic guide will be developed with input from public involvement co-applicants. The content of the topic guide will be based on information from the ToC framework as well as exploring barriers and enablers for those who have chosen not to participate and those who have completed a prehabilitation programme.

Interviews with professionals

Professionals' participant selection

After the ToC workshop, we will agree on which key stakeholders should be identified for interviews after the implementation of the PREHABS. We will select participants (n=10) with responsibility for the implementation, delivery or prehabilitation components. Consenting key stakeholders will take part in qualitative interviews to describe their experience of implementing the PREHABS.

Professionals' sample

We will describe the characteristics of the key stakeholders in terms of their job roles and responsibilities for delivering key aspects of the PREHABS.

Professionals' inclusion criteria

Key stakeholders with responsibility for the implementation strategy or that deliver or organise components of the intervention.

Professionals' interviews

In-depth qualitative interviews will be conducted with up to 10 professionals. A semistructured topic guide will be developed with input from the study management team, other stakeholders and public involvement. The interviews will take place in Leeds at an NHS site or at the University of Leeds (UoL). Interviews will be audio-recorded on an encrypted laptop or dictaphone.

Professionals' topic guide

A semistructured topic guide will be developed with input from key stakeholders. The content of the topic guide will be based on information from the ToC framework to identify progress towards short-term and long-term outcomes and the rationale and assumptions that were described at the start of the study. Key factors about the challenges of implementing this programme in practice will be explored.

Data management

The de-identified interviews will be transcribed by a professional transcribing agency recommended as the preferred provider by the UoL. Audio files and transcripts will be stored on a secure server at the UoL with limited access and password protection. Audio files will be deleted once they have been checked and verified.

Endpoints

The information from the ToC workshop will be used to revisit and enhance the feasibility and acceptability objectives of the PREHABS.

The data from the interviews will be used to provide insight from patients and professionals about enablers and barriers to the implementation of a tailored prehabilitation programme and to inform future research and service design.

End of the study

The end of the study is defined as the date the last registered participant reaches 12 months' postregistration, that is, the date of the last participant's 12-month follow-up visit.

Governance

Trial steering committee (TSC)

Independent oversight of the study will be conducted by the TSC. Among its members will be an independent chair, lay individuals and clinicians who are independent of the study research team. The TSC will meet twice a year.

Trial management group (TMG)

The TMG, comprising the Co-Chief Investigators and other key members of staff, including our lay partners,

are responsible for the clinical setup, ongoing management, promotion of the trial and interpretation of results. The TMG will meet quarterly.

Patient and public involvement

Patients will be involved at all stages of the PREHABS project, from inception to dissemination. A detailed summary describing how patients were involved with the design and delivery of the PREHABS has been published in our *paper, 'Integrating the patients' voice in designing and delivering a research study: The Yorkshire Cancer Research funded PREHABS study's experience'*.[37] Patient activities include:

- Co-designing the intervention delivery.
- The time and location for PREHABS interventions to take place.
- Advising on intervention acceptability.
- Writing of literature for patients.
- Finding motivators to engage our patients.
- Membership in the trial management and steering committees.
- Co-authors on grant applications, articles[37] and presentations.

Statistical considerations and determination of sample size

PREHABS is a feasibility study, and a formal power calculation was not required.[27] Instead, a pragmatic approach was adopted.

A review of the number of patients referred for curative radiotherapy for lung cancer for the year before the grant submission was undertaken. 262 patients from the Leeds postcode were treated with curative radiotherapy in 2017 (97 stereotactic ablative radiotherapy (SABR) and 165 non-SABR referrals), equating to 21 referrals a month (source: departmental statistics). Assuming that 50% of the approached patients accept and enter the trial, this equals approximately 10 patients per month. Thus, to demonstrate the feasibility of recruitment, the aim is to recruit a total of 90 patients. The study team is confident in recruiting this number as there is a successful track record of recruiting to target studies with a similar theme and patient cohort.

Analysis

Intervention study

Statistical analysis will be performed by statisticians from the Leeds Clinical Trials Unit, UoL. The qualitative analysis component will be performed by staff from the Research Development Service, UoL.

The analysis will focus on descriptive statistics and CI estimation rather than formal hypothesis testing; that is, no formal evaluation of the safety or efficacy of the study interventions will be conducted as part of this feasibility study.

In general, summary statistics (n (number of available measurements), arithmetic mean, SD, median, minimum and maximum) for quantitative variables and absolute and relative frequency tables for qualitative data will be presented.

Analysis of interviews from ToC embedded study

De-identified transcripts of the interviews will be imported into NVivo V.11[38] and analysed using a thematic framework analysis.[39–41] Two independent researchers will code the data for existing and emerging themes, and any differences will be resolved by consensus. The analysis will be further refined using a comparison and contrastive approach and the identification of negative cases.

Primary endpoint analysis

The primary endpoint analysis will be based on the population of participants registered within the 12-month recruitment period.

Treatment uptake and compliance

The number and proportion of participants starting each intervention will be summarised. The length of time between referral, intervention take-up and intervention compliance will be summarised and will include reasons for non-compliance where available.

Follow-up analysis

Participant retention during follow-up, including the number of participants withdrawing from the study and the timing and reasons for the withdrawal, will be assessed, and losses to follow-up will be reported.

Secondary endpoint analysis

The number of participants who stopped smoking will be summarised overall and at all time points. The 'want' of patients to quit smoking and the cost of smoking products will be analysed at the end of the 12-week smoking cessation programme and at follow-up clinical visits.

Exercise analysis will be conducted at the end of the study. An analysis of the Godin Leisure-time Exercise questionnaire, the SIT-Q-7d and the EBBS will be performed.

Outcome measures relating to QoL (Warwick-Edinburgh mental well-being, Euro-QoL (EQ-5D-5L), Patient Health Questionnaire (PHQ)-9 and European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30 scores) will be summarised overall and by time point.

An analysis of the dietetic metrics will be performed at the end of the study.

An analysis of the referrals to pulmonary rehabilitation will be completed to identify the number of patients referred, the length of time from referral and the number of patients that complete the programme.

Ethics and dissemination plan

Ethical approval was granted by the Cambridge East Ethics Committee on 12 May 2021. REC Reference: 21/EE/0048.

The study is registered in the NIHR portfolio (48420).

The results of the PREHABS will be written up and published for both academic and lay audiences. Articles will be published as peer-reviewed articles and presented at local and national conferences. Study outcomes will

also be presented at lay events such as 'Be Curious' UoL engagement events, Pint of Science and charity events.

Our public and patient partners will be included as authors[37] and invited to co-present with the study team.

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Contributors CB and KF are guarantors of integrity of the entire study and were responsible for study concepts and design. CB, AB, JCB, SB, MC, EM, RLM, SG-W, JH, GFW, CP, AS and KF prepared the manuscript. CB, AB, JCB, SB, MC, EM, RLM, SG-W, JH, GFW, CP, AS and KF edited the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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