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IMPROVE
Improving completion of PR

IMPROVE Trial: Improving completion of Pulmonary Rehabilitation with PR-Buddies

1. TITLE PAGE

Trial Title	Improving life quality in chronic obstructive pulmonary disease (COPD) by increasing uptake and completion of pulmonary rehabilitation with lay health workers: a cluster randomised controlled trial
Internal Reference Number / Short title	Improving completion of pulmonary rehabilitation with PR-buddies (IMPROVE)
REC Ref	22/NW/0330
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Date and Version No	4 January 2023, v.1.3

This protocol has regard for the HRA guidance and order of content

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There are no conflicts of interest among the trial research team

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, Health Research Authority (HRA), host organisation, and members of the Research Ethics Committee and Regulatory Authorities unless authorised to do so.

Trial Title: Improving life quality in chronic obstructive pulmonary disease (COPD) by increasing uptake and completion of pulmonary rehabilitation with lay health workers: a cluster randomised controlled trial

Protocol Date and Version No: 4/01/2023, v.1.3

Protocol signature page

The undersigned has read and understood the trial protocol detailed above and agrees to conduct the trial in compliance with the protocol.

Principal Investigator (Please print name)	**Signature**	**Site name or ID number**	**Date**
Co-Sponsor representative (Please print name)	**Signature**	**Co-Sponsor name**	**Date**
Co-Sponsor representative (Please print name)	**Signature**	**Co-Sponsor name**	**Date**

Following any amendments to the protocol, this page must be updated with the new protocol version number and date and re-signed by the site PI.

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3. KEY TRIAL CONTACT INFORMATION

Full title of trial	Improving life quality in chronic obstructive pulmonary disease (COPD) by increasing uptake and completion of pulmonary rehabilitation with lay health workers: a cluster randomised controlled trial
Trial Reg No	Add here [ISRCTN or Clinical Trials.gov]
Date of Registration	Add here
IRAS No.	308114
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Main trial sites	Pulmonary rehabilitation (PR) services - to be recruited after completion of internal pilot
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4. LAY SUMMARY

Chronic obstructive pulmonary disease (COPD) is the most common lung disease caused by smoking. It affects more than a million people in the UK. It causes breathlessness, cough, and fatigue. Flare-ups can lead to hospital admission. Pulmonary rehabilitation (PR) is the best treatment for the symptoms and impact of COPD. It improves quality of life and exercise capacity. PR classes include exercise and information on how to manage symptoms. More than 40,000 COPD patients are referred to PR each year in England, but the benefits of PR are limited by poor uptake. Only 4 out of 10 people with COPD, referred for PR, complete the classes. The reasons people don't go include travel issues, low mood, uncertainty about its benefits, and shame about smoking. Lay health workers (LHWs) are the key to this study. LHWs are effective in a range of health issues but they have not been used much in the NHS. Our COPD patient advisers call them 'PR-buddies'. COPD volunteers who have completed PR will be trained to be PR buddies (PRBs). They will support patients referred for PR. We have shown in previous research that PRBs can be recruited and trained to support COPD patients referred for PR. The PRBs were enthusiastic, committed volunteers, and patients welcomed their support.

Aims

We want to improve quality of life for people with COPD by increasing the number of patients completing PR. We want to know if trained volunteer PRBs are effective, efficient and acceptable in improving PR completion. We also want to know if recruitment and training of PRBs and setting up PR-buddy provision can be incorporated into PR services.

How we will do this

We will develop and test a training package for PR staff to introduce PR buddies in their services. We will measure the impact of the PRBs by counting the number of patients who complete a course of PR in 19 'PR-buddy' centres (intervention arm) around England compared with 19 'usual care' PR centres (control arm). In sites randomised to the intervention arm, volunteer PRBs will be people with COPD who have done PR. They will be trained in proven techniques (behaviour change techniques) to find out why people might not go to PR. When patients get an appointment to start PR, they will be put in touch with a PRB. Contact will be by phone but also by meeting up. For example, PRBs will offer to go with patients to their first PR appointment, if the patient would like them to. The PRBs will not go into the class with the patient.

The main outcome we will measure is the number of referred patients with COPD who complete PR. We hope that the support of a PRB will help more people to benefit from doing PR compared with the numbers finishing PR in the 'usual care' PR centres. Each part of the trial will be evaluated, including PR staff training, PRB training and the acceptability of the new PR-buddy service to patients, the volunteer PR-buddies, and PR staff in the centres that set-up a PR-buddy service.

5. SYNOPSIS OF TRIAL METHOD

The aim of the trial is to improve quality of life for people with COPD by increasing by 40% the number of referred patients completing PR with an LHW intervention. Further, the purpose is to show that the training and management of LHWs can be incorporated into PR services. IMPROVE is an open pragmatic cluster randomised controlled clinical trial of the impact of an LHW intervention on completion rates in PR centres throughout England. PR centres (clusters) will be randomised to intervention (LHW + usual care) or control arms (usual care only).

There are five Work Packages (WP) outlined below with the methods to be used and timelines for delivery:

WP1. Trial set up - months 1-8: Develop a training package for PR staff to recruit, train and manage LHWs in their PR centres. Refine the LHW training and intervention developed in the previous feasibility study (https://www.dovepress.com/getfile.php?fileID=48507). Recruit PR centres for the trial. Assess the impact of COVID-19 on PR delivery.

WP2. Internal Pilot - months 9-16: Randomise four centres, two to intervention and two to control, to assess PR staff training and LHW intervention delivery. Present outcome of Stop-Go criteria: delivery fidelity; LHW retention; and impact of COVID-19 on trial integrity; to Independent Trial Steering Committee for decision on progression - month 17.

WP3. Main trial – months 18 - 30: Continue trial in a further 34 PR centres, 17 intervention and 17 usual care. Primary outcome will be rate of completion in intervention sites compared to control sites.

WP4. Process evaluation: A range of elements will be evaluated, including PR staff training, LHW training, intervention fidelity, recruitment and retention of PRBs, characteristics of patient-participants, outcome of PR, acceptability to patients, LHWs, and PR staff,

WP5. Health economic evaluation.

Our COPD patient advisory group has been operating for more than eight years. Our PPI (patient and public involvement) co-applicant, has been closely involved in the intervention development and will be involved throughout the trial. The anticipated impact of the intervention is that the LHW intervention will enhance the delivery of PR, improve the efficiency of PR services and reduce waste.

The findings will be disseminated through patient and scientific meetings, a trial website, charitable and professional associations, press releases, and scientific publications.

Table 5.1 Tabular synopsis of IMPROVE trial method.

Trial Title	Improving life quality in chronic obstructive pulmonary disease (COPD) by increasing uptake and completion of pulmonary rehabilitation with lay health workers: a cluster randomised controlled trial
Short title	IMPROVE: Improving completion of pulmonary rehabilitation with PR-Buddies
Trial registration	Trial identifier, registry name, registration number and date of registration.
Co-Sponsors	King's College London Professor Reza Razavi Vice President & Vice Principal (Research) King's College London Room 5.31, James Clerk Maxwell Building 57 Waterloo Road London SE1 8WA reza.razavi@kcl.ac.uk Guy's and St Thomas' NHS Foundation Trust Great Maze Pond, London SE1 9RT, United Kingdom R&D@gstt.nhs.uk

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Funder	National Institute of Health and Care Research (NIHR) NIHR130999		
Clinical Phase	Phase III (effectiveness), and embedded Phase IV (implementation)		
Trial Design	Open pragmatic cluster randomised controlled clinical trial		
Trial Participants	Nominated staff from participating PR centres in the intervention sites, volunteer lay health workers, hereinafter called 'PR Buddies' or PRBs for short, and patient-participants.		
Sample Size	38 PR centres (randomisation by cluster), 1368 patient-participants		
Planned Trial Period	The total duration of the study is 36 months (3 years). The set-up of the study is expected to last up to 9 months, then the internal pilot is expected to last a further 7 months. The internal pilot will be followed by evaluation by the Independent Trial Steering Committee of the feasibility of the trial in terms of setting up and maintaining the intervention, and achieving the main milestones of the trial within the internal pilot. The research will proceed to the main trial if the ITSC and the funder agree. The main trial will take a further 19 months including trial evaluation and write up, health economic evaluation and process evaluation.		
Planned Site Recruitment Period	May 2022 – May 2023		
Planned Patient-Participant period	April to October 2023 (internal pilot) and September to April 2024 (main trial)		
Main Aim	**Primary Outcome**	**Outcome measures**	**Time point for assessment**
Improve the uptake and completion of pulmonary rehabilitation (PR)	Rate of completion of PR in participants in intervention sites compared to rate of completion of PR in participants in comparison/control sites	Site log of eligible referrals identified for the trial, as described in, Table 8.1. Rate of attendance at prescribed PR sessions. Uptake and completion as defined in Table 8.1	Month 33 (Main trial)
Secondary Aims	**Secondary Outcomes**	**Secondary Outcome Measures**	
Recruit and retain 38 PR centres	Proportion of the required 38 PR sites that was actually recruited and retained for the trial	Trial recruitment log of centres recruited and record of withdrawal or default.	Recruitment at month 13, Retention at month 26

Assess recruitment and retention of patient-participants	Proportion of the required target of at least 36 patient participants that was actually recruited and retained in intervention sites	Site log of eligible referrals identified for the trial, rate of acceptance of invitation to participate in the research, rate of assessment for PR and rate of participants followed through to completion. Uptake and completion as defined in Internal Pilot, Table 8.1.	Months 25-31
To compare the rates of improvement in exercise capacity, symptoms, quality of life and wellbeing	Standardised walking distance, respiratory-specific quality of life, psychological well-being.	Site records of 6MWD/ISWT, CAT/CRQ-SAS, PHQ9, GAD7 or HADS as assessed routinely by PR teams at baseline and 6 months Mailed/online questionnaires to collect questionnaire elements not collected by the PR teams and six-month review.	Exercise capacity tests at pre-PR assessment and assessment at end of PR By mail/online (or if preferred, telephone) questionnaire assessment at baseline, 3 months and 6 months following PR assessment. For 3 and 6 months assessments and questionnaires, visit windows of -2 weeks +4 weeks will be permitted.
Assess the characteristics of participating patients	Demographic and clinical characteristics of patient participants in all participating sites	Data collected and recorded on CRFs (paper or online) at recruitment and consent interview.	Internal pilot months 11-13, main trial 20-25
Intervention(s)	PR staff in services randomised to the intervention arm will set up and run a PR-buddy service. Designated staff from the PR teams will be trained to recruit, train and monitor volunteer PR-buddies (PRBs). The PRBs will be		

	trained by the PR staff to demonstrate the benefits of PR, to support people newly referred to the service and to help them overcome the perceived obstacles to taking part. Volunteer PRBs will be recruited from among people with COPD who previously successfully completed PR in the participating PR services. They will contact newly referred patients before their first assessment in PR. They will support patients' participation in PR through remote and/or face to face meetings and may accompany the patients to their initial PR assessment. PR staff will manage and support the group of PRBs through monthly group meetings.
Comparator	The comparator in this trial is usual care without support of PRBs. The standard of care is laid out in international guidelines.(1) Usual care (standard of care) of delivery of PR will be no different between intervention and control sites.

6. ABBREVIATIONS

AE	Adverse event
AR	Adverse reaction
CAT	Chronic Obstructive Pulmonary Disease Assessment Test
CI	Chief Investigator
COPD	Chronic Obstructive Pulmonary Disease
CRF	Case Report Form
CRQ-SAS	Chronic respiratory questionnaire, self-administered standardised
CRN	Clinical Research Network
CTU	Clinical Trial Unit
CTRG	Clinical Trials and Research Governance
DMP	Data Management Plan
EoI	Expression of Interest
GAD-7	the Generalised Anxiety Disorder assessment test
GCP	Good Clinical Practice
GP	General Practitioner
GSTT	Guy's and St Thomas's NHS Foundation Trust

HE	Health Economic
HEAP	Health Economic Analysis Plan
HADS	Hospital Anxiety and Depression Scale
HRA	Health Research Authority
ICF	Informed Consent Form
ID	Participant unique study identifier
ITSC	Independent Trial Steering Committee
ISWT	Incremental Shuttle Walk Test
KCL	King's College London
KCTU	King's Clinical Trial Unit
KORDS	King's Open Data Resource System
LHW	Lay Health Worker
MMRC	Modified Medical Research Council breathlessness questionnaire
MI	Motivational Interviewing
NHS	National Health Service
NIHR	National Institute for Health and Care Research
PHQ-9	the Patient Health Questionnaire
QALYs	Quality-adjusted life years (QALYs)
PI	Principal Investigator
PIS	Participant/ Patient Information Sheet
PLICS	Patient-level Information and Costing System
PPI	Patient and Public Involvement
PR	Pulmonary Rehabilitation
PRB	Pulmonary Rehabilitation-Buddy (PR-buddy).
R&D	NHS Trust R&D Department
RCT	Randomised Controlled Trial

REC	Research Ethics Committee
RSI	Reference Safety Information
SAE	Serious Adverse Event
6MWD	Six-minute walking distance
SAP	Statistical Analysis Plan
SAR	Serious Adverse Reaction
SIV	Site Initiation Visit
SITE PI	Site Principal Investigator
SDV	Source Data Verification
SMPC	Summary of Medicinal Product Characteristics
SOP	Standard Operating Procedure
SRF	Senior Research Fellow
SUSAR	Suspected Unexpected Serious Adverse Reactions
TMF	Trial Master File
TMG	Trial Management Group

7. BACKGROUND AND RATIONALE

7.1. COPD and pulmonary rehabilitation

Chronic obstructive pulmonary disease (COPD) is the most common lung disease caused by smoking.(2) It affects more than a million people in the UK. COPD causes breathlessness, cough, and fatigue. It is a major cause of emergency hospital admission in the NHS, with rates having changed little in 20 years.(4) COPD is the fifth cause of mortality in the UK, and is a priority for the NHS in its long-term plan.(5, 6) COPD is commonest among people who live in deprived areas.(7)

Pulmonary rehabilitation (PR) is the most effective treatment for the symptoms and disability of COPD.(1) The effectiveness of PR in improving quality of life, exercise capacity, and symptoms and disability in COPD has been demonstrated conclusively in a longstanding Cochrane review now closed.(8) PR classes include exercise and self-management. More recently it has been associated with improved survival in the year after discharge from hospital (9). Intensive hospital outreach with PR has been associated with reduced risk of admission.(10)

Pulmonary rehabilitation is a low-risk intervention. A recent systematic review of sixteen trials of pulmonary rehabilitation in patients undergoing an acute exacerbation found that adverse events had

been reported in only four trials.(11) Three patients suffered 'more serious' adverse events, all of which were due to underlying co-morbidities.

7.2. The problem

The American Thoracic Society and the European Respiratory Society have jointly called for funding and collaboration between clinicians, patients and funders to improve implementation of PR in health services.(12) Despite high quality evidence of its effectiveness, only 40,000 of the 500,000+ people with COPD for whom PR is indicated in the UK are actually referred.(13) Among those who are referred for PR, rates of completion of PR are only 40% due to poor uptake.(12-14) In England, 62% of the 40,000 referred to PR each year take up the treatment but only 65% of those complete it.(2)(15) The reasons behind low uptake and completion of PR are well known. They include lack of perceived benefit by participants, travel issues, referrers' uncertainty of its effectiveness, inconvenient timing, current smoking, and depression.(16, 17) The reasons why people don't complete the treatment include travel issues, low mood, uncertainty about its benefits, and shame about smoking.(16, 17) To tackle the low rates of receipt of PR, referral to PR has become a new target in the NHS Quality and Outcomes Framework in primary care.(18)

Interventions to improve uptake and completion of PR have been mainly components of packages to improve overall COPD care.(19, 20) The interventions have included computer-based prompts at review, provision of patient information or care manual, education of clinicians, financial incentives, and use of a wireless tablet with web connection. There have been reports of moderate success with two high intensity interventions to improve uptake and completion, but the quality of the studies has been low. Harris et al (2009) showed an increased uptake with an individualised care-plan.(21) Zwar et al (2012) showed a higher uptake of PR by patients who received individualised COPD care at home by a nurse specialist.(22) A recent Cochrane review of a diverse range of alternative interventions to achieve higher physical activity in COPD showed none to be effective (23). At present, pulmonary rehabilitation is alone, among non-pharmaceutical remedies, in improving outcomes in COPD.

7.3. The intervention – Lay Health Workers (PR-buddies)

Lay health workers (LHWs) are 'any health worker carrying out functions related to healthcare delivery, trained in some way in the context of the intervention, and having no formal professional or para-professional certificate or tertiary education degree'.(24) Their effectiveness in therapeutic interventions in various health settings has been shown in many studies particularly in improving uptake and adherence to proven treatments.(25-27) In the US, LHWs are often known as 'patient navigators'.(27) In a systematic review, McBrien et al reported on 54 randomised controlled trials (RCTs) of patient navigators of which one was conducted in the UK.(27) Among the advantages of using LHWs are their shared social backgrounds with patients, shared personal experience of the health issue, and less pressure on their time compared to clinicians.(28).

LHWs are at the core of this study.(24) COPD volunteers who have completed PR will be trained as LHWs and will support patients referred for PR. We have shown, in a feasibility study, that LHWs can be recruited and trained to support these patients.(29) LHWs were enthusiastic, committed volunteers, and patients welcomed their support.(28) LHWs are effective in a range of health issues but have been little used in the NHS.(27)

The concept of an LHW intervention to promote uptake and completion of PR for people with COPD was first raised with our Patient and Public Involvement Group in 2013. The form of LHW intervention proposed was of people with COPD who had completed PR and were willing to undertake training for the role providing information based on their knowledge and experience together with emotional support to newly referred patients. The basic element in the intervention is one of supportive communication. The group had the strong view that LHWs should be volunteers since they were likely to have had much benefit from the treatment. With the support of our patient advisory group we tested and demonstrated the feasibility (NIHR-RfPB PB-PG-0213-30052; REC Reference: 14/LO/2313) of an intervention based on LHW support modelled on the Theory of LHW working.(28-30) The LHW support was delivered using targeted evidence-based behaviour change techniques taught to the LHWs.(31) The fundamentals of behaviour change using behaviour change techniques (BCTs) are described in the Capability, Opportunity, Motivation and Behaviour (COM-B) theoretical model.(32-34) The classification of BCTs has been derived by Michie et al.(33) The same team has linked BCTs with targeted outcomes.(35) Our co-applicant Godfrey has conducted a trial of training of physiotherapists using the same theoretical basis.(36-38) The advantages of using LHWs include shared social backgrounds with patients, shared personal experience of the health issue, and less pressure on their time compared to clinicians.(30) Mediating those changes through LHWs was a key outcome of our feasibility study.(29) Obstacles to participation in PR were mapped to relevant BCTs and identified by an expert consensus. After providing training and support to patients, LHWs were retained and remained committed. The enthusiasm of the LHWs was striking and both LHWs and patients reported the strength of the common bond as a key to the intervention.(31)

The implementation-based intervention development used in this trial is an approach described by O'Cathán et al (2019) in an MRC-NIHR funded study to ensure that the delay between the evaluation of effectiveness and intervention delivery is minimised in terms of avoidable cost and complexity.(39) We have linked the intervention with its implementation by placing it in the hands of PR staff in PR centres. The fundamental response is the LHW PR intervention. By using this implementation-based intervention development we are minimising the cost of putting the intervention into practice. The cost of the trial would be more expensive in itself if the intervention was driven by the research team alone.

The intervention under examination in this trial is one of supportive communication between trained PR-buddies and patients with COPD newly referred for pulmonary rehabilitation. No adverse events were reported in the feasibility study. The opportunity for the intervention to lead to harm to patient-participants or the PR-buddies themselves is minimal. The minimisation of risks and burden to the PRBs and patient-participants, including to carers and to professionals, is explained in Section 12. Among the risks we have considered are the sense of disappointment or responsibility that may be experienced by PRBs or by patients when patients drop out of PR. Disappointment with the quality of the relationship between PRBs and patient-participants may have similar impacts. As with every clinical trial, serious unexpected suspected adverse reactions (SUSARs) to the intervention may occur and will be managed appropriately (Section 12). Risk to researchers visiting patients' homes or to PRBs meeting patient-participants by phone or in person has been addressed in our adoption of the King's College London fieldwork guidelines, particularly the guidance on lone-worker risk prevention (which follows the guidance outlined in https://www.nhsemployers.org/sites/default/files/media/HSWPG-Lone-Workers-staff-guide-210218-FINAL_0.pdf). PR-buddy training will include the boundaries of the role. It will be emphasised that PR-buddies should only agree to meet patients in public places such as cafés.

7.4. Findings from the feasibility study

In the feasibility study for this trial, we tested the recruitment, training and intervention delivery of the LHWs in improving uptake and completion of PR.(29) The key feasibility outcomes relevant to the main trial were: (i) 110 (40%) of COPD patients experienced in PR informed about the trial, expressed interest in the volunteer role; (ii) 20 entered training; (iii) 12 took part in the intervention and remained active and committed until the end of the study; (iv) mailed invitations to referred patients to take part in the trial received a very low response; telephone invitations were accepted by 30%; (v) LHWs confirmed the acceptability of the volunteer role; (vi) there was a high degree of intervention delivery fidelity; (vii) the LHW role was acceptable to LHWs and participants; (viii) LHWs and participants valued the common bond between them; (ix) LHWs would have been happy to spend more time in training.(28, 29, 31)

We have shown that LHWs can be recruited and trained in targeted evidenced-based BCTs that relate to their experience.(29) The training techniques and processes tested in the feasibility study will be the basis of the PR staff training in the trial. BCTs have been used successfully in promoting change in exercise.(37) Mediating those changes through LHWs was a key element of our feasibility study.(29) After providing training and support to patients, LHWs were retained and remained committed. To maximise the engagement of the LHWs we established an explicit agreement between them and the institution, King's College London, with clear statements of roles and responsibilities on both sides. In keeping with the agreement, we provided ongoing group mentoring sessions throughout the programme to share experiences and provide opportunities for group problem solving. Patients supported by LHWs had rates of completion that were 15 percentage points higher than usual rates in those PR centres.(29) The enthusiasm of the LHWs was striking and both LHWs and patients reported the strength of the common bond as a key to intervention success.(28) The LHWs preferred the term 'PR-buddies' to describe their role. We have used the terms PRB and LHW where appropriate in this protocol. For the most part they should be seen as interchangeable. Following the study five PR-buddies (PRBs) and one patient-participant joined our COPD patient and public advisory group.

7.5. The study population and theoretical background

The population to be studied in the trial will be COPD patients recently referred for PR. Most patients with COPD are over 45 years of age. Most come from relatively deprived backgrounds and completed their education at or before age 16. Most live in rented accommodation. About 40% continue to smoke. Most are likely to have other co-morbidities. The demographic, social and clinical description of the study population is relevant to the preparation of research literature that will be provided to participants, and also to the design of the training and the preparation of training materials.

Volunteers for the PR-buddy (PRB) role will be sought from COPD patients who have successfully completed PR within the previous 12 months at the participating PR centres. We know from the feasibility study that they will have much in common with the patient participants, an observation that was described in the feasibility study by PR-buddy and patient-participants as a 'common bond'.

To plan the intervention to improve low uptake and completion of PR with PRBs, we used the theory of LHW working.(30) The method combined peer-supported (LHW) identification of obstacles to PR participation with practical approaches to overcoming them including demonstrating the benefits of PR. We chose behaviour change techniques (BCTs), utilising the COM-B model of change with Michie's behaviour change wheel, to develop a structured approach to the identification of obstacles and practical methods to overcoming them.(33-35) From the known obstacles to completion of PR we

identified BCTs suited to exploring those obstacles together with BCTs suited to overcoming them. Obstacles to participation in PR were mapped to relevant BCTs and identified by an expert consensus.(34, 35) A menu of BCTs with the two elements, obstacles and approaches to overcoming them, was composed.(31) The menu of BCTs became a central element of the training programme for LHWs in the feasibility study for this trial.(31)

7.6. The logic model for the trial

Pulmonary rehabilitation (PR) is the best treatment for the symptoms and impact of COPD. It improves quality of life and exercise capacity. However as outlined previously the benefits of PR are limited by poor uptake and completion. The reasons people don't complete PR are well documented, this trial aims to improve quality of life for people with COPD by increasing the number of referred patients completing PR with a lay health worker (LHW) intervention.

Searches for a literature review in the trial funding application were conducted in PubMed and Web of Science with the search terms COPD, pulmonary rehabilitation, lay health workers, community health workers, patient navigators, completion, uptake, cost, cost benefits, cost-effectiveness, in various combinations and including studies of all types. Relevant trials were sought in the WHO ICTRP, but that is not currently available due to overload of the system following COVID-19. Search of the ISRCTN, Clinical Trials.gov, and EudraCT registries showed no relevant ongoing clinical trials or other studies. We have found no evidence of testing of established interventions to improve uptake and completion of PR. Early and colleagues have published the protocol for a mixed methods study, funded by NIHR (PB-PG-1215-20034) with the aim of developing a toolkit that could be used with referred patients to improve uptake and completion.(40) The study will have preparatory phases investigating the views of health care professionals and patients before developing the toolkit.

The schematic Improve Trial Logic Model (Figure 7.1) shows the response that the trial design makes to the obstacles to PR uptake and completion.

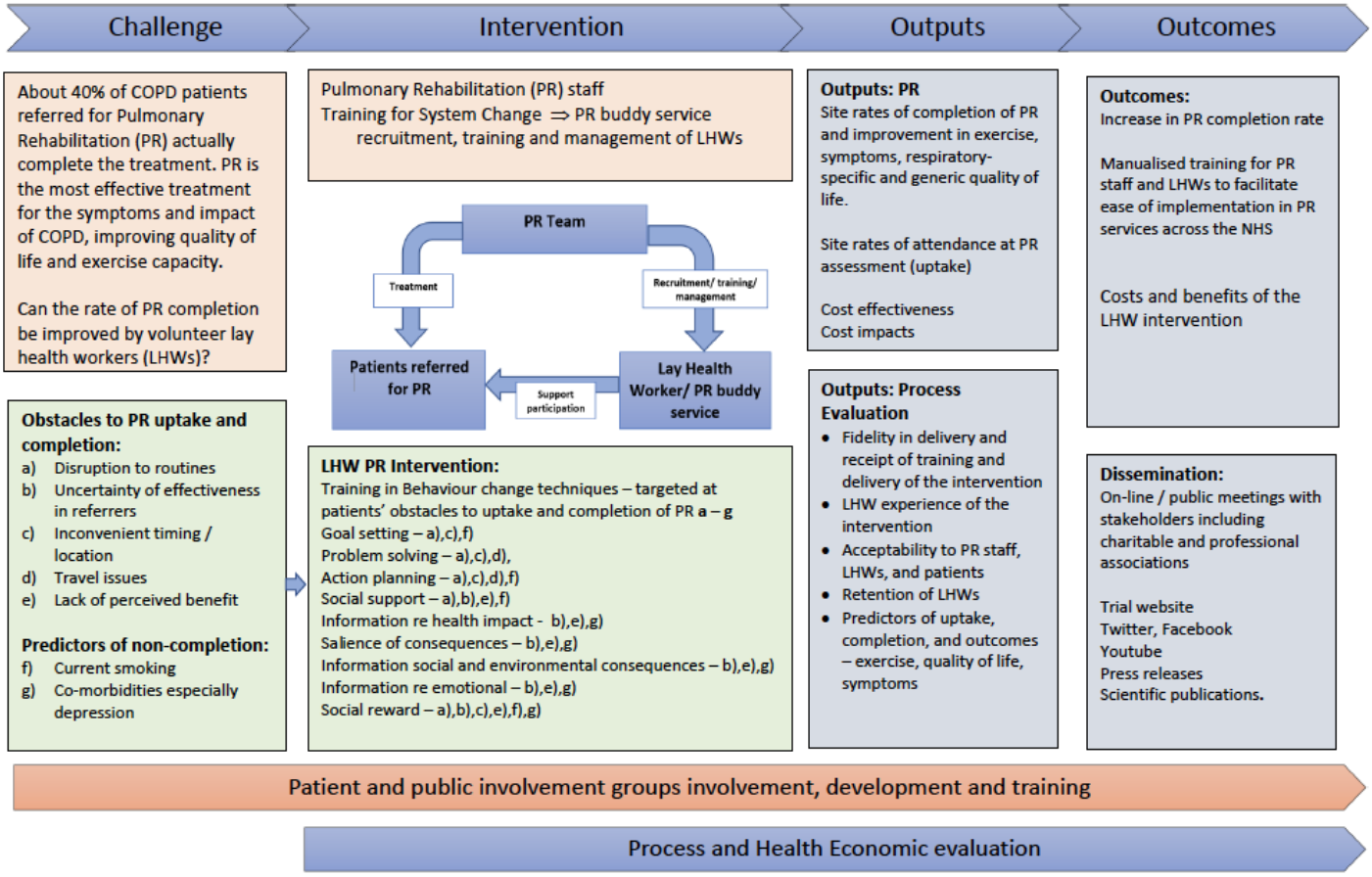


Figure 7.1 Improve Trial Logic model

The intervention, under the schematic, shows a specific response to each of the known obstacles and predictors of non-completion of PR. The PR staff have the role of recruiting, training and supporting the LHWs for which they themselves will be trained. The process evaluation will assess every stage of the trial beginning with the training of the PR staff and ending with the predictors of uptake and completion. The economic evaluation of pulmonary rehabilitation will be the first conducted since 2001.(41)

The LHW will support the patient throughout the treatment cycle from before the initial assessment until attendance has been established, and if appropriate until the treatment has been completed. LHW support is designed to counteract failure to attend at first attendance and subsequent attendance attrition.

7.7. The receptiveness of NHS services to the trial

In our pre-trial telephone survey of 42 PR services in England to assess interest in the proposed trial, five sites reported using COPD patients who had previously completed PR and were then recruited as buddies in their PR programmes. These were usually individual volunteers working singly within the PR classes. In Grimsby, North Lincolnshire, a long established advanced programme of PR buddies who work alongside patients and PR staff in classes is run by a Community Benefit Society called Care Plus.(42) They provide training and support for their PR volunteers. The programme has not been formally assessed. Care Plus is a Charitable Trust. The manager of this innovative service has welcomed our interest and has agreed to explore with us the elements of their approach that would be relevant to the

trial, including their agreement with volunteers and the training they provide. She has joined our trial stakeholder group.

We conducted a pre-trial telephone and email survey of PR sites in England June 2020. Many were unavailable due to redeployment of staff during the COVID-19 pandemic crisis. 38 of 42 sites we were able to contact expressed interest in taking part in the trial. Several sites were continuing their services remotely offering telephone or remote conferencing as a mode of delivery. One site was conducting home assessments at the beginning of a programme of PR run by telephone or video communication. Sites that had been in contact with patients reported that most patients had no access to the internet either through patients having no Wi-Fi at home or not having access to a computer or smart phone. It seems likely that remote delivery of PR will prove inaccessible for most referred patients.

The COVID-19 pandemic has led to the suspension of many services only some of which are back delivering PR. We will be investigating the degree to which services have returned to normal delivery and we will include their status in randomisation with minimisation.

8. TRIAL DESIGN, OBJECTIVES AND OUTCOME MEASURES

8.1. Trial design

The IMPROVE trial is an open pragmatic cluster randomised controlled trial of an intervention in England. The trial evaluates a complex intervention following the Medical Research Council (MRC) framework.(43) The intervention is based on the deployment of volunteer lay health workers, called pulmonary rehabilitation buddies (PRBs), in pulmonary rehabilitation (PR) services to improve the uptake and completion of the treatment by people with COPD. The trial will take place in PR services in England with wide geographical distribution. It is a mixed Phase III and Phase IV testing the effectiveness and pragmatic implementation of the intervention.

As described in section 5 above and shown here in Figure 8.1, there will be five stages or work packages (WP) in this research:
WP1: Preparatory work and intervention refinement; WP2: Internal pilot; WP3: Main cluster randomised controlled trial; WP4: Nested process evaluation; and WP5: Health Economic Evaluation.

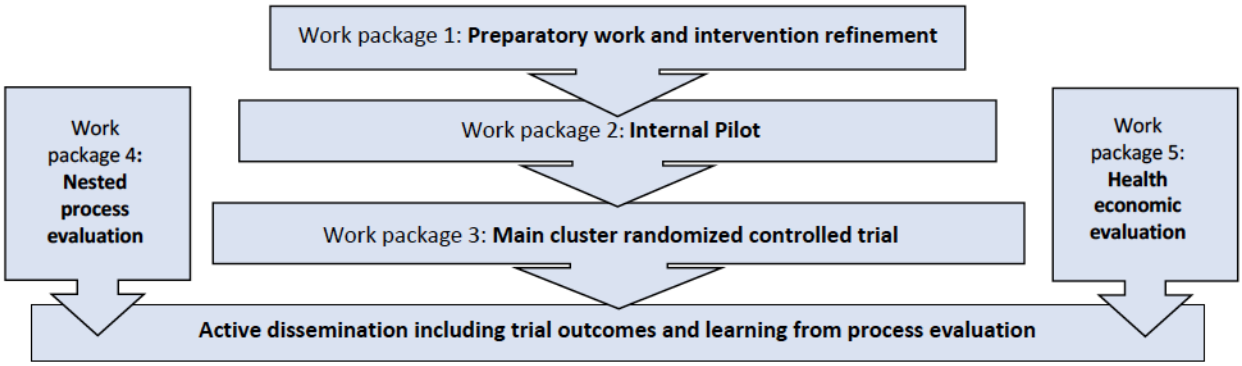


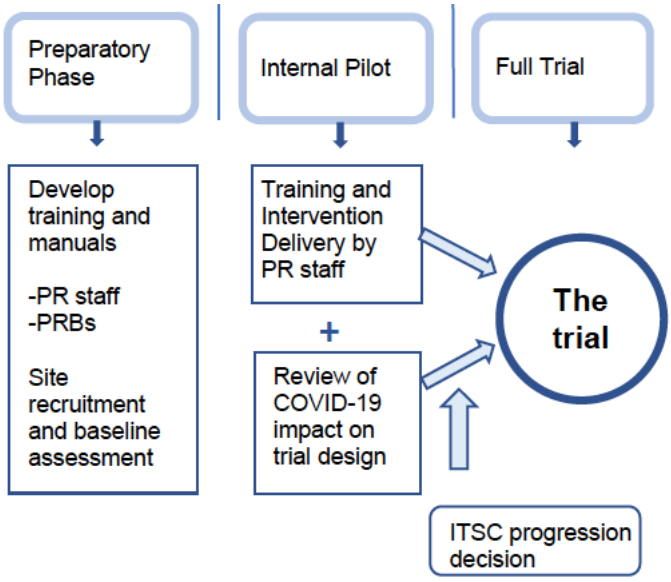
Figure 8.1 Structure of the IMPROVE trial

For the flowchart of the clinical trial see Appendix A. For the Gantt chart, see Appendix D.

Work package 1, the preparatory work for the trial will include the development and refinement of the intervention, the acquisition of governance and ethical approval, the design of the case report forms, and the recruitment of participating sites.

Work package 2, the internal pilot, will test the elements of the intervention developed since the feasibility study including the training package for PR staff to recruit, train and manage PRBs in their PR centres. The impact of COVID-19 on the trial design will be assessed at the same time. Both the implementation during the pilot and the impact of COVID-19 will be included in progression criteria to be presented to an Independent Trial Steering Committee (ITSC) at a 16-month check point (see Section 10.8). Four PR sites, two randomised to the intervention arm and two to the control arm, will take part in the internal pilot to test the implementation of the PRB intervention (Figure 8.1). The intervention arm sites will undertake PR training for 3 staff who will then be responsible for recruitment, training and supervision of a group of PR-buddies. The control arm sites will act as a comparator to the intervention sites and will not run a PRB service. Success in implementation will be determined by recruitment and training of at least 6 PR-buddies and support of at least 2 patients per PR-buddy in each intervention site over three months.

Integrity of the trial design after the COVID-19 pandemic will be assessed by comparing the capacity of the service after the pandemic with that prior to the pandemic, together with the acceptability to the PRBs of training in groups, and the safety of providing that training. The role of the internal pilot in the overall design is presented schematically in Figure 8.2.



PR = pulmonary rehabilitation PRB = PR-buddies ITSC = independent trial steering committee

Figure 8.2 Internal Pilot

If the internal pilot demonstrates the feasibility of the trial in terms of the implementation of the recruitment, training, deployment and retention of PRBs and adequate re-establishment of PR services

after the COVID pandemic, it is expected the Trial Steering Committee will recommend continuation of the trial.

Work package 3, the main trial, work package 3, will begin after the internal pilot. The study aims and objectives are encapsulated in the main trial and described in Section 8.2.1.

Work packages 4 and 5. The trial has two embedded elements, the process evaluation, work package 4, and the health economic evaluation, work package 5.

Further information about how the trial will be carried out is described in section 10.

8.2. Trial aims, objectives and outcome measures

The aims, objectives and outcome measures of the trial are presented in the following order:

Internal pilot aims, outcomes and outcome measures (work package 2)
Main and secondary aims, outcomes and outcome measures (work package 3)
Process evaluation, outcomes and outcome measures (work package 4)
Health economic evaluation, outcomes and outcome measures (work package 5).

8.2.1 Internal pilot aims, outcomes and outcome measures (work package 2)

The purpose of the internal pilot is to demonstrate the feasibility of conducting the trial in four trial sites, two in the intervention arm and two in the control arm, and with specific reference to the training of PR-staff in the recruitment, training and ongoing support and management of PR buddies (PRBs) in the two intervention sites. The geographical areas of the sites that will be approached in the pilot study (as well as the main study) are detailed in Section 10.1.1.3. Sites that will be recruited to the pilot study will be chosen based on how quickly they can obtain confirmation of capacity and capability and/or proximity to the research team, based on the Chief Investigator's discretion. The pilot will also show the viability of the trial in the context of the COVID-19 pandemic. The outcomes will be presented to the Independent Trial Steering Committee (ITSC) for their assessment of the acceptability and appropriateness of the continuation of the trial. The ITSC will present its findings to the funder. The outcomes to be assessed are shown in Table 8.1. The criteria for progression of the trial are tabulated in section 10.8.

Table 8.1 Internal pilot aims, outcomes and outcome measures

Internal Pilot	Pilot Outcomes	Pilot Outcome Measures	Time point for assessment
Test recruitment, training and retention of PRBs	Proportion of the required target of PRBs, minimum six per site, that was actually recruited, trained and retained in 2 internal pilot intervention sites.	Site log of invitations sent, formal expressions of interest, number of telephone interviews, and face to face selection interviews with volunteers. Site log of volunteers entering training, completing PRB training, doing the intervention, and being retained to the end of pilot.	Month 16
Test recruitment and retention of patient-participants	Proportion of the required target of 2 patient participants per PRB that was actually recruited and	Site log of eligible referrals identified for the trial, rate of acceptance of phone-invitation to participate in the research, rate of obtaining consent to participate	Month 16

	retained in 2 internal pilot intervention sites	by Clinical Research Network (CRN) teams. Rate of participants followed through to completion of PR. Uptake is defined as attendance at PR assessment appointment. Completion is defined as attendance at 70% of prescribed PR sessions.	
Assess impact of COVID on service capacity and the potential achievement of the required recruitment at the time of entry to the trial	Proportion of pulmonary rehabilitation services' expected capacity for referred patients suitable for the trial that were actually offered places. (COVID-19 impact)	Site records of rates of referrals and assessments over three months before baseline data collection compared with three months pre-pandemic.	Months 10-12
PRB characteristics	Demographic and clinical characteristics of PRBs in 2 internal pilot sites.	Site logs	Month 11
PRB rate and mode of contact with patient-participants	Rate and mode of contact (phone and/ or face to face) between PRBs and patient-participants in 2 intervention sites	Counting of rate and mode of contact between PRBs and patient-participants in PRB phone recordings and PRB logs	Months 15-16
Experience of setting up and running PR-Buddy service from staff perspective	Obtain feedback and insights relating to their experience of setting up a PR-buddy service and to identify factors that might influence the operation and effects of the intervention across sites in the main trial.	In-depth qualitative interviews with PR-staff from internal pilot sites	Months 15-16

8.2.2 Main and secondary aims, outcomes and outcome measures of the main trial (work package 3)

The main aim of the trial is to improve the uptake and completion of PR in COPD patients newly referred for PR. The uptake and completion of PR will be measured as a rate in each cluster. A cluster is defined as a participating PR service (i.e., research site). Rates of uptake and completion will be compared between intervention and control sites. Completion of PR is defined as attendance at 70% of sessions. Uptake is defined as attendance at the initial pre-PR assessment (Table 8.2).

Secondary outcome measures, in relation to the intervention, are the rates of recruitment and retention of PR sites; the rates of recruitment and retention of PR-buddies; rates of recruitment and retention and characteristics of participating patients. Secondary outcome measures in relation to patient-participants are quality of life; exercise capacity; and symptoms.

Table 8.2 Main and secondary aims, outcomes and outcome measures of the main trial (work package 3)

Main Aim	Primary Outcome	Outcome measures	Time point for assessment
Improve the uptake and completion of pulmonary rehabilitation (PR)	Rate of completion of PR in participants in intervention sites compared to rate of completion of PR in participants in comparison/control sites	Site log of eligible referrals identified for the trial, as described in, Table 8.1. Rate of attendance at prescribed PR sessions. Uptake and completion as defined in Table 8.1	Month 33 (Main trial)
Secondary Aims	**Secondary Outcomes**	**Secondary Outcome Measures**	
Recruit and retain 38 PR centres	Proportion of the required 38 PR sites that was actually recruited and retained for the trial	Trial recruitment log of centres recruited and record of withdrawal or default.	Recruitment at month 13, Retention at month 26
Assess recruitment and retention of patient-participants	Proportion of the required target of at least 36 patient participants that was actually recruited and retained in intervention sites	Site log of eligible referrals identified for the trial, rate of acceptance of invitation to participate in the research, rate of assessment for PR and rate of participants followed through to completion. Uptake and completion as defined in Internal Pilot, Table 8.1.	Months 25-31
To compare the rates of improvement in exercise capacity, symptoms, quality of life and wellbeing	Standardised walking distance, respiratory-specific quality of life, psychological well-being.	Site records of 6MWD/ISWT, CAT/CRQ-SAS, PHQ9, GAD7 HADS Mailed/online questionnaires to collect questionnaire elements not collected by the PR teams.	Exercise capacity tests: at pre-PR assessment, assessment at end of PR By mail/online (or if preferred, telephone) questionnaire assessment at baseline, 3 months and 6 months. For 3 and 6 months assessments and questionnaires, visit windows of -2 weeks +4 weeks will be permitted.
Assess the characteristics of participating patients	Demographic and clinical characteristics of patient participants in all participating sites	Data collected and recorded on CRFs (paper or online) at recruitment and consent interview.	Internal pilot months 11-13, main trial 20-25

6MWD = six-minute walking distance ISWT = incremental shuttle walk test
CAT = Chronic Obstructive Pulmonary Disease Assessment Test
CRQ-SAS = Chronic Respiratory Questionnaire Self-Administered Standardised

HADS = Hospital anxiety and depression scale

8.2.3 Process Evaluation aims, outcomes and outcome measures (work package 4)

The overall aim of the process evaluation is to ensure the reasons for the intervention working or failing have the best likelihood of being analysed and explained. The objectives of the process evaluation are:

a) to assess the quality and fidelity of the delivery of the various components of the intervention: training design, training delivery, training receipt, and enactment of both the training of PR staff and PRBs
b) investigating the acceptability of the intervention to PR staff, to supported patients and to PR-buddies
c) to identify factors that might influence the operation and effects of the intervention across different trial sites
d) to inform the process of implementation in real world settings and roll out across the NHS

These objectives will be achieved through a range of measures (Table 8.3). Details of data collection are described in section 8.4 below. The process evaluation will begin in the internal pilot and continue through to the main trial.

Table 8.3 Process evaluation aims, outcomes, and outcome measures

Process Evaluation Aims	Process Outcomes	Process Outcome Measures	Time point for evaluation
Recruitment and retention of PRBs	Proportion of the required target of 6 - 12 PRBs that was recruited and retained in each of 19 intervention sites.	Site log of invitations sent, formal expressions of interest received, and number of telephone and face to face recruitment interviews completed. Site log of volunteers entering training, trained PRBs doing the patient support, and retention to end of trial.	Months 9-16 and 22-30,
Recruitment and retention of patient-participants	Proportion of the required target of 2 patient participants per PRB that was actually recruited and retained	Site log of referrals, recruitment to trial, completion of follow-up telephone assessments by research assistants	Months 28-30
Impact of COVID on service capacity at time of entry.	Proportion of PR services' original expected capacity for referred patients that was actually offered places after COVID-19	Site records of rates of referrals and assessments in three months pre-baseline compared with three months pre-pandemic.	Months 19-20
PRB characteristics	Demographic and clinical characteristics of PRBs in 19 intervention sites.	Completion of demographic information by site teams	Months 20-24
PRB rates of contact	Rate of contact (phone and/or face-to-face) between PRBs and patient	Counting of rates of contact between PRBs and patient-participants in PRB phone recordings and PRB logs	Months 25-30

	participants in 19 intervention sites		
PR-staff training delivery fidelity	Fidelity of research team delivery of training to PR staff in 19 intervention sites	Review of training manuals and training plan, checklist of training elements delivered, 20% random sample analysis of recorded training (day 2 delivered via MS Teams), register of attendance noting latecomers or participants that leave early. Also, qualitative interviews (n=22-24) with sample of PR staff completed at end of intervention period across a range of intervention sites.	Months 20-32
PR-staff training receipt fidelity	Fidelity of receipt of training by research team to PR staff in 19 intervention sites	Training review (completed at end of day 3), assessment of fidelity of delivery of PRB training by training PR staff	Months 20-32
PRB training delivery fidelity	Fidelity of delivery of training by PR staff to PRBs in intervention sites	Checklist of training elements delivered, recording and observation of at least ½ day of training delivery (preferably completed by different member of research team to those delivering PR-staff training), register of attendance noting any latecomers or participants that leave early for contact time. Also focus groups n = 6-10 (completed at end of intervention period) at a PRB support meeting	Months 20-32
PRB training receipt fidelity	Fidelity of receipt by PRBs of training delivered by PR staff	Group discussion following training videos and case studies (day 2 of training). Training review/ quiz (completed at end of day 3)	Months 22-24
PRB intervention delivery fidelity	Fidelity of delivery of the patient-support element of the intervention to patient participants by the PRBs	Analysis of mode and frequency of contact with supported patients from PRBs recordings (20% random sample of recordings analysed for content by listening to recordings) Also qualitative interviews (n=22-24) with sample of patients across a range of intervention sites.	Months 26-30

Intervention acceptability to PR-staff	Acceptability of the intervention of setting up and running a PRB service to PR staff in 19 intervention sites	Qualitative interviews with PR staff (n=22-24) completed at end of intervention period across a range of intervention sites. Questionnaire assessment of PR staff	Months 26-32
Intervention acceptability to PRBs	Acceptability of the PRB role, recruitment and training process to PRBs in 19 intervention sites	Focus groups n = 6-10 (completed at end of intervention period) at a support meeting. Questionnaire for PRBs at sites where focus groups not held	Months 26-32
Intervention acceptability to patients	Acceptability of the PRBs support to patient-participants	Qualitative interviews (n=22-24) with sample of patient-participants (intervention sites) End of study questionnaire for patient-participants in intervention arm	Months 26-32
Predictors of uptake and completion	Factors that influenced the effectiveness of the intervention	Multiple linear regression of site completion rates with range of predictors on site characteristics, PRB characteristics and activity, patient-participant reports.	

8.2.4 Health economic outcome evaluation (work package 5)

The overall aim of the health economic evaluation is to conduct a within-trial cost-effectiveness and cost-utility analysis, from the perspective of the NHS and personal social services (NHS & PSS) as well as that of the society, and if the intervention is found effective in increasing the completion of PR, to undertake longer-term cost-effectiveness and budget-impact modelling.

The within-trial analysis will require the assessment of resource use and costs: a) for set-up of the intervention; b) for delivering the intervention through the NHS; c) of patient participants and PR-buddies; d) of health and social service use during the intervention and follow-up period; d) and the quality-adjusted life years of patient participants – EQ-5D-5L. These data will be collected through trial case-record forms, administrative health, and project records and patient-completed questionnaires. We will review the responses obtained during the internal pilot, and if substantive changes are required we will seek a protocol amendment. If longer-term economic evaluation and budget-impact modelling are required, data will be supplemented using literature reviews and publicly available data. These are summarised in Table 8.4.

How these data, along with patients' demographic information and instrumental variables will be used for economic evaluation are explained in Section 13.10.

Table 8.4 Health economic objectives, outcomes, outcome measures, and time points for assessment

Health Economic Evaluation Objectives	Health Economic Outcomes	Methods of Measurement[1]	Time points for Measurement
1. To assess set-up costs of the intervention	Cost of setting up the intervention, e.g., recruitment (PR staff, PR-buddies, patients), training (PR staff, PR-buddies), DBS checks (PR-buddies)	• Log, kept by each site, of recruitment activities including written invitation, and initial telephone / face to face interview with the PR-buddies seeking consent • Log of set-up training attendance by PR staff and PR-buddies	Months 9-13 and 18-24.
2. To assess the delivery costs of the intervention to the NHS and personal social services (PSS)	Cost of activities to deliver the intervention, e.g., setting up appointments by mail and phone; phone and face-to-face patient support	• Trial log of telephone and mail contact with referred patient-participants, on allocation of PR-buddies • Log of telephone and email contact with PRBs, on support and mentoring. • Logs of telephone and face-to-face contacts between PR-buddies and patients. • Health service log of pulmonary rehabilitation attendance held by the PR teams (also captured as trial primary outcome measure) • Health resource use questionnaire for patients.	Months 21-30
3. To assess cost to PR buddies	Time costs to PR-buddies e.g., to attend training or supervision meetings with staff or patients. Money costs borne by PR-buddies e.g., to attend training or supervision meetings with staff or patients.	• Log of set-up and training attended by PR-buddies • Expenses claims by PR buddies for transportation or refreshments. Frequency and duration of PRB contacts with patient-participants (recorded)	Months 12-16 and Months 21-30
4. To assess costs to patient participant	Time costs to patients e.g., to attend PR sessions, to meet PR-buddies, to access health and social services, or other activities to be determined through interview. Money costs borne by patient participants e.g., to attend PR sessions, to meet PR-buddies,	• Log of pulmonary rehabilitation attendance held by the PR teams (also captured as trial primary outcome measure) • Log of telephone and face-to-face contacts between PR-buddies and patients. • Health Resource use by patients – health resource use questionnaire.	Months 12-16 and Months 21-30 (period of intervention with patient-participants

	to access health and social services, or other activities to be determined through interview.		
5. To assess the cost of health and social service utilization by patient participants	Cost of healthcare utilization by patient participants include primary care (e.g., in-person / phone / home visits to GP surgery), and secondary care (e.g., out-patients, visits to A&E, and hospital length of stay)	• Health Resource use by patients – health resource use questionnaire	Months 12-16 and Months 21-30
6. To assess the QALYs of patient participants	QALYs of patient participants will be assessed using area under the curve method, based on EQ-5D-5L administered at three time points within 6 months (baseline, 3-months, 6-months).	• EQ-5D-5L	Months 12-16 and Months 21-30

[1] Will be reviewed at internal pilot.

8.3. Trial setting

The trial will take place in Pulmonary Rehabilitation (PR) Services in England. Invitations to participate will be focused on services in 5 areas initially: Yorkshire and Humber; Greater Manchester; West Midlands (excluding Wales); London and the South-East (Kent, Surrey and Sussex); in order to maximise the representativeness of the trial in terms of urban, suburban and rural settings, socio-economic deprivation, and ethnic variety, and to maximise the efficiency of the research process. These geographical areas will be consistent with the clinical research networks (CRN) covering the 2 London networks and 4 other networks as listed above, along with some sites in Greater London that fall under CRN North Thames, and sites that are present in Surrey that are covered by CRN Thames Valley and South Midlands. Site recruitment may be extended to the remainder of England if there are difficulties recruiting sufficient sites. Participating PR services will have to meet the inclusion and exclusion criteria (see section 9.2). In the event of more than 38 services seeking to participate, characteristics of services will be assessed to make the participating services as representative as possible of PR service delivery in England as a whole. More than 35 services have expressed interest prior to the research having been funded. They were widely distributed between London, Gloucestershire, West Midlands, the North-West and Yorkshire.

8.4. Data Collection

The way in which the data will be managed are described in the Data Management section (section 14) below. A wide range of data types and collection measures are described in the Trial Aims, Outcomes and Outcome Measures (section 8.2) above. The processes involve: data collection from routinely

collected data in trial sites; training course assessments including training reviews/quizzes, recorded training, attendance registers, and questionnaires; questionnaires of patient participants; recorded interactions between PRBs and patient participants; focus groups with PRBs; qualitative interviews with PR staff and patient-participants.

8.4.1 Baseline PR service data

As soon as a PR service is confirmed as a site in the IMPROVE trial the method in use for recording rates of referral for PR, uptake rates and completion rates for PR relating to COPD patients will be checked for reliability and that they are kept up-to-date. Uptake is defined as attendance at pre-PR assessment appointment. Completion is defined as attendance at 70% of prescribed PR sessions. Patients found unsuitable for participation at pre-PR assessment should be removed from the denominator for completion.

The collection of these baseline data will be assessed by a member of the research team and will usually occur within 2 weeks of the site initiation visit (SIV) or as soon after as practicably feasible. It is anticipated that where possible most SIVs will be completed in person, so this check will be in person.

8.4.2 Secondary outcome measures of exercise capacity, respiratory-specific quality of life, psychological well-being.

Assessments of exercise capacity, respiratory-specific quality of life, and psychological well-being are carried out routinely in PR services at baseline and at final assessment. The results of these measures will be collected in patient-participants in both sides of the trial. Two measurements of exercise capacity are widely used, the six-minute walking distance (6MWD) and the incremental shuttle walk test (ISWT). Equally two measures of quality of life, the Chronic Obstructive Pulmonary Disease Assessment Test (CAT) and the Chronic Respiratory Questionnaire Self-Administered Standardised (CRQ-SAS), the CAT is more widely used. Three measures of psychological well-being, the Patient Health Questionnaire PHQ-9, the Generalised Anxiety Disorder (GAD-7) assessment test and the Hospital Anxiety and Depression Scale (HADS), the former more commonly used. We will not prescribe which of these measures should be used as PR teams will have well established processes. Standardised comparisons will be made between the walking tests. A questionnaire assessment will be made at baseline, at three months and at six months. This will be directed at the health economic analysis (see section 8.2.4), and will include the CAT and HADS in those patients in whom the CRQ-SAS, PHQ-9 and GAD-7 were used as part of the PR team assessments.

8.4.3 Training of PR-staff, assessment of fidelity of delivery and receipt

Training of designated PR-staff in the intervention sites will be delivered by the research team over 2 ½ days. Tests of fidelity will include a review of the training plan and manuals, a checklist of training elements delivered by the research staff and integrated assessment exercises linked to the learning outcomes to show successful completion of training. Day 2 of PR-staff training will be delivered and recorded (with consent), 'remote live', via MS Teams (trainers and trainees attending simultaneously). Analysis of a 20% random sample of the recorded training in each site will be completed by members of the research team not involved in the training. Test of fidelity of receipt of PR-staff training will be based on group discussion during the training and a training review completed at the end of day 3 of the PR-staff training which is the day that will be delivered in person. Fidelity of receipt of PR-staff training and enactment will be demonstrated in the delivery of the PRB selection, training by the PR staff.

Qualitative interviews (n=22-24) with a sample of PR staff will include gathering feedback on the training as part of a wider range of topics. These will be completed at the end of the intervention period as part of the process evaluation (interview topic guide attached to IRAS application). Interviews will be conducted by research staff experienced in qualitative data collection. With participants permission interviews will be recorded on encrypted digital voice recorders for verbatim transcription and analysis.

8.4.4 Logging of PR service data (uptake and completion of PR for trial participants)

PR-staff in intervention and usual care sites will keep contemporaneous attendance records at pre-PR assessment and subsequent PR classes for trial participants.

8.4.5 Logging process of selection, recruitment, training and support of PRBs

Recruitment, selection and training of a group of PR-buddies will be the responsibility of the designated PR staff in intervention sites. Each element will be noted on digital or paper site logs. Designated PR staff will be trained in the processes of data recording with respect to the selection, recruitment, training and support of PRBs. Data recording templates will be in the PR staff training manual, with electronic versions provided for ease of completion. Volunteers who are interviewed for the PRB role will be asked to provide demographic and clinical characteristics as part of the selection process when they complete an application form. The data will be required to report on the PRBs' characteristics and to allow subsequent contact to collect data on experience of the PRB role.

A register of attendance at training by the PRBs will be kept. Volunteers who fail to attend without contacting the PR staff will be followed up by phone. Where possible, training sessions missed will be made up by a combination of video call, self-directed learning from the PRB manual and by early or late attendance at the next training day. This final element will help to answer outstanding questions and to ensure that the PR-staff can assess the progress of the PRB against criteria for successful completion of training.

8.4.6 Tests of fidelity of delivery and receipt of the PR-buddy training and implementation

Training of PRBs in the intervention sites will be delivered by the PR teams over 3 days. Tests of fidelity of the training intervention with PRBs will include a review of the training plan and manuals, a checklist of training elements delivered by the PR staff and integrated assessment exercises (group discussions and training review/ quiz) to show successful completion of training. Half of day 2 of PRB training will be observed, and recorded with consent, by a member of the research team. This will not be the same research staff who delivered the training for the PR-staff. Tests of fidelity of delivery of the PRB training will be based on independent analysis of a sample of the recording and training elements delivered during the observation. Focus groups at between 6 and 10 of the sites will be completed at the end of the intervention period to gather feedback on the PRB experience of the training as part of a broader discussion as part of the process evaluation.

Assessment of the enactment of the PRB training will be based on analysis of recorded interactions between PRBs and patient-participants, the keeping of logs of contacts, and on qualitative interviews with patient-participants after completion of six-month follow-up. These will be completed at the end of the intervention period as part of the process evaluation (interview topic guide attached to IRAS application). Interviews will be conducted by research staff experienced in qualitative data collection. With participants permission interviews will be recorded on encrypted digital voice recorders for verbatim transcription and analysis.

8.4.7 Recruitment and retention of patient-participants

Recruitment of patient-participants will be completed jointly by the PR staff at each site and the local clinical research networks (CRN). PR staff will log phone calls made to referred patients all of whom will be considered potential patient-participants. The proportion that express interest and agree to their contact details being passed to the local CRN staff will be noted. CRN staff will be responsible for following up by telephone or email (depending on individual preferences) to answer any questions potential participants might have. CRN staff will log the posting or e-mailing of participant information sheets (PIS) and completion of informed consent meetings including where potential patient-participants decline to give consent once their questions have been answered. If the site has a dedicated research administrator/nurse available to work on this trial, then they may take over some or all of the CRN staff member's duties in recruitment as described in this sub-section. Completed logs relating to the recruitment of patient-participants will be passed to the central research team on a monthly basis by encrypted email with password protected attachments.

Numbers of patient-participants allocated to PRBs and frequency of contacts between PRBs and patient participants will be assessed logs kept by the PRBs and recordings of PRB-patient-participant encounters which will be made securely on the trial smart phones lent to PRBs for this purpose. The smart phones will be procured by a supplier approved by King's College London procurement team, and they will be supplied to the PRBs by a member of the central research team.

8.4.8 Health Economics evaluation

The trial logs, kept at each site, of recruitment activities with PRBs including written invitations, telephone and face-to-face interview, attendance at training and attendance at mentoring/support, and also of telephone and face-to-face contacts between PRBs and patient-participants will be key elements of the health economic evaluation. In addition the recordings of interactions between PRBs and patient-participants will be analysed to account for their frequency, duration and mode (telephone or face-to-face). The PR health service log will provide information on attendance at PR. Finally data on health service usage (health resource use questionnaire) and the EQ-5D-5L will be obtained at baseline, three months and six months.

8.4.9 Qualitative interviews and focus groups

The purpose of the qualitative elements of the process evaluation are to investigate and understand in more detail:

a) Experiences of PR-buddies and of PR staff of intervention delivery, reported obstacles and facilitators, and investigation of relevant contextual and environmental factors
b) Retention of PR-buddies and factors affecting retention
c) Shared experience of illness between PR-buddies and participants, and evidence of the role of a common bond between PR-buddies and participants (a key finding of the feasibility study)
d)Experience and acceptability of the intervention from the different perspectives of each participant group: PR teams, PR-buddies and patients
There will be 4 parts to the qualitative data collection. Firstly, one-to-one interviews with PRBs who drop out of training or during the intervention period at their site; secondly one-to-one interviews with a sample of designated PR staff from intervention sites, thirdly one-to-one interviews with a sample of patient participants and finally focus groups with some of the groups of PR-buddies (conducted at their final support meeting towards the end of the intervention).

Interviews and focus groups will be digitally audio recorded using encrypted devices. Permission to record interviews and focus groups will be sought on the consent form. Recordings and transcripts will be stored on password protected computers at King's College London (KCL). During the transcription process any identifiable information mentioned in the interview will be removed from the interviews.

Transcription will be carried out by the research team or an experienced, KCL approved, transcription company. All copies of audio recordings sent to the transcription company will be destroyed following transcription.

A summary of the assessments and an overview of the recruitment steps in the trial can be found in Appendix F.

9. STUDY PARTICIPATION AND WITHDRAWAL

This section of the protocol presents a description of the trial sites, the pulmonary rehabilitation teams, the PR-buddies (PRBs), and the patient participants.

9.1. Trial Sites and participants

9.1.1 Trial sites

Pulmonary rehabilitation (PR) teams that express an interest in the trial and meet the inclusion and do not fit any of the exclusion criteria will be eligible to take part in the trial. The trial is a pragmatic trial but in addition it has unusual implications for participating PR staff. The intervention includes elements that test the efficacy of the central component of the intervention, the support of referred patients by pulmonary rehabilitation buddies (PRBs). It also includes elements that test the capacity for the intervention to be implemented in usual care PR. The PR staff will therefore be delivering the intervention but will also be research subjects in that they will be observed and assessed as they deliver the intervention. Thirty-eight PR sites in total are required to carry out the trial: four of these will be recruited in the pilot study (WP2) and an additional thirty-six sites will be recruited in the main study (WP3). All sites from the main study in both arms will be used in the analysis that will place as part of WP4 and WP5.

9.1.2 PR-buddies

In sites randomised to the intervention arm, PRBs will be recruited from the PR services in which they will volunteer as PRBs. They will be identified within the PR service as having recently completed PR. They will not necessarily be actively receiving treatment in the NHS. Up to twelve trained PRBs will be required in each site in the intervention side of the trial.

9.1.3 Patient Participants

The patient-participants will be recruited from the PR services to which they have been referred as patients seeking treatment for their COPD. Their eligibility for treatment will not be influenced by their identification as potential research participants. Should they decide not to participate there will be no disadvantage in terms of the speed with which they are invited for pre-PR assessment. Thirty-five patient-participants will be required in each PR service taking part in the trial.

9.2. Inclusion Criteria

9.2.1 Category A - Participating PR sites – assuming the site understands and agrees that it will be randomised to either the intervention or usual care arm of the trial.

1. can complete >15 PR assessment appointments per month to allow for at least 36 participants to be recruited over six months.
2. conduct routine baseline and final PR session data including uptake and completion rates, quality of life assessment (COPD Assessment Test-CAT or Chronic Respiratory Questionnaire -CRQ-SAS), exercise tests (Six Minute Walking Distance - 6MWD or Intermittent Shuttle Walk Test - ISWT), and well-being assessment (General Anxiety Disorder Assessment 7 – GAD7) and (Patient Health Questionnaire 9 -PHQ9 or Hospital Anxiety and Depression Scale HADS).
3. completion rate ≤55% determined by count based on appropriate referrals received or completion rate ≤65% determined by count based on patients who attended first assessment. Referrals of non-COPD chest problems and patients with significant other disabilities that prevent participation should not be included in the completion rate denominator. The decision to limit inclusion to sites with completion rate of 55% or less relates to the priority given to service inequalities and the need for the NHS to have a threshold for the introduction of the intervention. Including all sites may diminish the opportunity to show a difference in those services in greatest need.
4. agree to randomisation to intervention or usual care
5. agree to include all eligible patients in the invitation to be randomised for the PRB intervention or usual care.
6. agree to release three PR staff for training (not simultaneously) over 2 days with additional half day remote training
7. agree that two PR staff will undertake intervention delivery
8. agree third PR staff member to have a back-up role in event of a colleague becoming ill or leaving the service during recruitment and LHW training.
9. at least two of three participating staff members to be a registered healthcare professional (HCP)
10. if third member is a non-HCP, then should be at least Band 4 NHS payscale
11. one or more members of the PR team have at least one year's experience in PR

9.2.2 Category B - Intervention site participating team members

1. Aged 18 years or above
2. be employed member of staff within the PR service at the intervention site
3. willing to undertake 2 ½ days training to train, recruit, manage and support PRBs
4. willing to manage and support PRBs over a nine-month period
5. willing to take part in research activities including keeping accurate records

9.2.3 Category C - Pulmonary rehabilitation buddy volunteers (PRBs)

1. Aged 18 years or above
2. COPD diagnosis and PR completion within previous year
3. volunteer for the role
4. willing to undertake training and be supervised by the PR team
5. willing to support at least 6 PR patients over 9 months
6. able to travel independently
7. agree to use encrypted smart phones (after training) for recording conversations with supported patients

9.2.4 Category D - Participating Patients

1. Aged 18 years or above
2. COPD diagnosis

3. referred to PR service
4. Medical Research Council (MRC) breathlessness score > 2
5. consent to be randomised to intervention or usual care arm of trial
6. consent to receive telephone contact by PRB and to meet when appropriate
7. consent to give personal details to research team
8. consent to give research team information on attendance and routinely collected data

9.3. Exclusion Criteria

9.3.1 Category A - Participating PR sites

1. unable to join trial until after June 2023
2. unable to identify at least three members of staff for the trial willing to consent to participation
3. local trust R&D office unwilling to support the trial

9.3.2 Category B - Site participating staff

1. will not be expected to be employed in their post for the duration of the trial at the site in question

9.3.3 Category C - Pulmonary rehabilitation buddy volunteers

1. unable to participate for the duration of the trial at the site in question
2. unable to travel independently to meet referred patients
3. unable or unwilling to use a smart mobile phone
4. unable to give valid consent
5. failed DBS check
6. female patients who are pregnant or breastfeeding
7. not deemed suitable to work with patient-participants (occupational health form) as assessed by a healthcare professional

9.3.4 Category D - Participating-patients

1. poorly controlled angina on minimal exertion
2. myocardial infarction in 6 weeks prior to consent to the trial
3. breathlessness as a result of cardiac disease.
4. uncontrolled hypertension
5. any medical problem that severely restricts exercise or compliance with the programme e.g. severe arthritis or dementia
6. unable to give valid consent
7. female patients who are pregnant or breastfeeding

9.4. Study Withdrawal

Participation in the study is fully optional and a decision to not participate by either the PRB or the patient participant will not affect their care in the future. PRBs and patient participants are free to withdraw from the trial at any stage without an obligation to give a reason for their withdrawal. Withdrawal from the trial will not affect their legal rights or any future care.

Any participant who expresses a desire to withdraw will be invited to complete the follow-up data collection questionnaires, however this is optional. The invitation to complete these questionnaires will be offered verbally as part of the same conversation requesting withdrawal. Any individual who expresses a desire to withdraw will be removed from the trial at the earliest possible opportunity. They

will be made aware that their data up to the point of withdrawal will be retained for research purposes until the end of the trial.

10. TRIAL PROCEDURES

10.1. Recruitment of Trial Participants

As detailed in the previous section there are four groups of participants in the IMPROVE trial. The eligibility criteria and exclusion criteria of these four groups are listed in section 9 of this protocol. In this section the recruitment of the trial sites and participants will be described in the same order as they are listed here:

1. Trial sites
2. Individual PR staff at trial sites (sites randomised to the intervention arm)
3. Volunteer PR-buddies
4. Patient-participants

For an overview of trial recruitment, please see Appendix A.

Step towards recruitment of site
Promote IMPROVE trial to pulmonary rehabilitation (PR) centres that are potential trial sites. As this is a pragmatic trial, sites will be selected from areas in England initially.
Services interested asked to complete expression of interest (EoI) form and return to IMPROVE research team.
Check eligibility criteria against information provided on returned EoI form.
Introductory meeting (in-person or video call) to discuss mechanisms, workload, back filling of staff hours, processes of the trial for intervention and control arms.
Liaise with local trust research & development (R&D) department and PR lead to review site agreement.
Liaise with site's local Clinical Research Network regarding recruitment of patient participants and capacity and capability assessment.
After receipt of HRA approval arrange site initiation visit (SIV), in-person or video call depending on preference of site.
Completion of site agreement.
Randomisation.

10.1.1 Recruitment of trial sites

Sites in the IMPROVE trial will be pulmonary rehabilitation (PR) centres that meet the eligibility criteria detailed in section 9.2 and 9.3, and whose PR team agree to be randomised to either arm of the trial; that is either:

a) intervention delivery (setup of a PR-buddy service) or
b) care as usual

Promotion of the fact that the IMPROVE trial has been funded and that recruitment has opened to PR centres to participate as sites in the trial will take place using existing contacts, the trial stakeholder group, PR networks and relevant professional organisations (for example the Association of Chartered Physiotherapists in Respiratory Care and the Primary Care Respiratory Society newsletters). PR centres will be asked to make informal expressions of interest directly to the research team. It will be made clear that at this stage getting in touch does not commit the centre. They will have the opportunity to get more detailed information and ask questions before deciding if they want to proceed to enter into a site agreement. A site information leaflet (based on the plain English and scientific summaries from funding application) will be provided by email. This will provide potential sites with information about the trial, make it clear that they have to agree to be randomised after an agreement to participate is made

An exploratory phone or video call meeting will be arranged with PR sites expressing interest to assess suitability and eligibility. Suitability assessment will include availability of data for baseline assessment of uptake and completion rates in all sites; assessment of site systems for patient recruiting, routine data collection, delivery of PR in terms of waiting time from referral to assessment, interval between assessment and first PR class, number of PR classes offered each patient, intervals between classes, and opportunity for re-joining treatment if sessions are missed (e.g. through illness or family responsibilities).

As formal EoI forms are received, a member of the central research team will log the forms in the Trial Master File (TMF) and use the information provided by the PR centres to do a definitive check for eligibility for the trial. Once site eligibility has been confirmed the central research team will:

a) contact the Trust R&D department regarding the site agreement and support they can offer to the PR centre including any local research nurses who may be available to help with recruitment. Note: we anticipate that we may recruit PR centres who have not been involved in a research trial before and are therefore not familiar with the support that they can expect from their R&D department.

b) contact the local Clinical Research Network (CRN) regarding support for recruitment of patient participants and capacity and capability assessment.

c) send a site agreement for review by the site and PIS for review by the staff who will become designated staff.

d) arrange an introductory meeting (in-person or video call) between the site and member(s) of the research team to discuss mechanisms, workload, back filling of staff hours, processes of the trial for intervention and control arms and prepare for the site initiation visit (SIV).

10.1.1.1 Site initiation visit

Site initiation visits (SIVs) will be completed by member(s) of the research team in-person or remotely, depending on the preference of the site. During the visit, the rates of referral and rates of uptake and completion will be verified. The same presentation slides will be used at all SIVs for consistency and to ensure all sites are fully informed. Training will be provided for the nominated members of the PR team staff on adverse event reporting, and standard data collection needed for the trial. The SIVs will also

cover in detail systems for and the importance of record-keeping (referral rate, delegation logs, how they record uptake and completion of PR) and the importance of not introducing other initiatives that may impact on uptake and completion of PR during the trial.

10.1.1.2 Randomisation of sites

IMPROVE is a pragmatic, cluster randomised controlled trial. Randomisation will be carried out at the level of PR centres and will take place during or as soon after the site initiation visit as practical.

The specific description of the randomisation is given in Section 10.4.

PR staff in sites randomised to the intervention arm in the trial will:

- Receive training from the central research team in training PR-experienced patients to be PR-buddies
- Select and recruit PR buddies (see Table 10.2)
- Present training material (prepared by the central research team) to PR-experienced patients who would like to become PR-buddies
- Participate in recruitment of patient-participants (see Table 10.3)
- Collect data on recruited patient-participants' attendance at PR sessions and screening and recruitment logs
- Hold monthly PR-buddy support meetings
- Conduct routine PR assessments (as per standard of care)
- Collect and record any adverse events from PR-buddies and patient participants, and report any Serious Adverse Events (SAEs) to the central research team at King's College London (see section 12)

Sites randomised to the control arm will not be running a PR-buddy service. However, they will still recruit patients to the study (as per Table 10.3) and the PR staff will be asked to collect data on recruited patient-participants' attendance at PR sessions and screening and recruitment logs and provide these to central research team. They will also be asked to conducting routine PR assessments (as per standard of care), collect and record any adverse events from PR-buddies and patient participants, and report any Serious Adverse Events (SAEs) to the central research team at King's College London (see section 12).

10.1.1.3 Location of trial sites

All the trial sites will be pulmonary rehabilitation centres in England. There will be 4 sites in the internal pilot (two randomised to intervention and two to usual care). In the main trial there will be a further 34 PR centres, 17 intervention and 17 usual care. The PR centres will be selected from within 5 regions of England initially:

- ✓ Yorkshire and Humber
- ✓ Greater Manchester
- ✓ West Midlands (excluding Wales)
- ✓ London
- ✓ South East (Kent, Surrey and Sussex)

Recruitment will be extended to the remainder of England if site recruitment is slow or insufficient sites are identified. Large PR centres may be considered for inclusion as more than 1 trial site if PR is run in discreet locations by different staff and each location meets the eligibility criteria on its own merits. For

example, adjacent towns where PR is delivered by a single large NHS Trust may be considered for inclusion as 2 trial sites.

10.1.2 Recruitment of individual PR staff at trial sites randomised to intervention arm

Three individual PR staff will be recruited to the trial as participants in the trial sites randomised to the intervention arm. The eligibility criteria for these 3 PR staff are listed in the previous section of this protocol in subsections 9.2 and 9.3. They need to be experienced in the delivery of PR and 2 out of the 3 should be registered health care professionals. These 3 staff participants will be responsible for implementing the intervention of setting up a PR-buddy service at the site which is described in detail in Section 11 of this protocol.

During the exploratory phone call or video meeting with PR centres expressing interest in participating as a trial site, the requirement for 3 individual PR staff at trial sites randomised to the intervention arm to consent to becoming trial participants will be explained. This is a pragmatic trial and in reality the members of staff may be nominated by their manager. However, once the outcome of randomisation for the site is known the 3 designated members of staff in intervention sites will be provided with the latest approved version of the PIS for PR staff. A member of the research team will take written informed consent from the 3 members of the PR team using the latest approved version of the Informed Consent Form (ICF) (Section 10.3.1) after the PR staff members have had the chance to ask any questions. This may be done remotely working to an approved system for taking remote consent. If a staff member does not wish to participate in the trial, even if their manager says they should, then that PR centre will not be used as a site unless a suitable third member of staff can be nominated and consents to the study.

10.1.3 Recruitment and selection of PR-buddies (intervention sites only)

The steps in the recruitment of volunteer PR-buddies are summarised in table 10.2 below (also see Section 11.2.2. for description of recruitment as an element of the intervention).

Table 10.2 Stages in recruitment and selection of volunteer PR-buddies.

Step towards recruitment of PR-buddy **Action by Trial site**	**Action by volunteer**
PR teams write to people with COPD who completed PR in the last 12 months to invite them to volunteer as a PR-buddy. Short information sheet may be provided to people with COPD at end of PR assessments during the recruitment period. Target number of previous PR patients to be approached: n=100 - 125.	
Log all expressions of interest about PR-buddy role and subsequent steps listed below.	Potential volunteers to respond to PR team if interested in learning more about PR-buddy role.
Follow-up phone call to all interested respondents to answer any questions and complete screen for eligibility. Decide if to offer interview or not.	Respondents to speak with PR team member on the phone, explain reason(s) for volunteering.

If less than 25 people express interest in volunteering extend the recruitment process to more potential participants.	
Send information about PRB training and role to suitable volunteers and then invite suitable applicants to an in-person selection interview.	Read information about PRB training and role.
Write an acknowledgement to any volunteers not offered a selection interview and include signposting to local volunteer services that may have suitable alternative volunteering opportunities for them.	
Complete selection interviews with volunteers.	Complete interview.
Invite selected interviewees to PR-buddy training confirming selection for training by email or letter seeking written acceptance of offer.	Confirm intention to take up place on PR-buddy training, bring suitable documents to confirm their identity to the first training day.
Obtain evidence of Disclosure and Barring Service (DBS) check for those volunteers offered a training place.	
Write to any volunteers not offered a training place following interview to include signposting to local volunteer services that may have suitable volunteering opportunities for them	
Phone call to any volunteers who do not confirm they will take up the PR-buddy training place offered	

Rows of the table shaded in yellow are optional dependent on response

The eligibility criteria and exclusion criteria for PR-buddies are listed in detail in Section 9.1.2. The recruitment and selection of suitable volunteers for the PR-buddy role will be the responsibility of the staff participants from the PR team who are trained to work on implementation of the IMPROVE trial (hereafter referred to as designated PR staff). The stages in the recruitment and selection of volunteer PR-buddies are listed in table 10.2 above. The designated PR staff will log all the stages at their site including how many people they provide with the short information sheet; how many are screened by phone; how many are interviewed; and how many are offered training places. Templates to log this data will be provided to the designated PR staff during their IMPROVE trial training for PR staff. These logs will be stored in the site file and anonymised data shared with the central IMPROVE trial research team.

10.1.3.2 Selection interviews for volunteers interested in the PR-buddy role

Two of the designated PR staff will conduct individual, in-person selection interviews for volunteers interested in the PR-buddy role. Training in relation to the selection of PR-buddies will be included in the training received by the designated PR staff. The purpose of the selection interviews is for the designated PR staff to decide on the suitability of volunteers to progress to the PR-buddy training.

The interviews will be informal and each one is expected to last approximately half an hour. Volunteers will be offered reasonable travel expenses to attend. The designated PR staff will explain to each volunteer that the interview will be a two-way process. Volunteers will receive information to help decide whether they want to commit to the PR-buddy role. Designated PR staff will learn about the suitability of volunteers to carry out the PR-buddy role. The interview will have a number of elements:

- The designated PR staff will ask the volunteer about their own experience of completing PR.
- The designated PR staff will explain the two elements of the PR-buddy role in the IMPROVE trial:
  a. volunteer role supporting patient-participants – part of the selection interview will be used to ascertain that the volunteer understands the time commitment required to attend training and then to support patients referred to PR.

  b. research - explaining the use of IMPROVE trial phones for recording for the research the conversations between the PR-buddy and supported patients; and the focus groups (topic guide attached) to be held with the group of PR-buddies at trial sites as part of the process evaluation.
- A scenario will be used to explore what the volunteers thinks their responsibility would be if a patient that they were supporting told them something confidential.
- The volunteer will be given the opportunity to ask questions.

10.1.3.3 Volunteer agreements and DBS checks

If the volunteer is assessed as suitable for the PR-buddy role at interview, meets the study criteria and is willing to commit to the requirements of the PR-buddy role they will be offered a place on the PR-buddy training course. This will be confirmed in writing (post or email depending on individual preference). In addition to details about the PR-buddy training (dates, time and venue) volunteers successfully completing a selection interview will be sent:

1. Detailed Participant Information Sheet (PIS)
2. Volunteer agreement**

A written copy of the latest approved version of the PIS for PR-buddies will be sent to volunteers who are offered a place on the PR-buddy training following a selection interview (see section 10.3.2 above). This will detail the exact nature of the IMPROVE trial; what it will involve for the participant; the anticipated benefits and any risks involved in taking part; details of the Chief Investigator and local site Principal Investigator (PI). More details in relation to the taking of informed consent are given at section 10.3.2 below.

**We have a detailed but clear volunteer agreement which lays out the roles and responsibilities of both the volunteer PR-buddies and the PR-centres in which they will be based. The purpose and content of the volunteer agreement will be explained during the first morning of the PR Buddy training during which the trainee PR buddies will also get an opportunity to ask any questions that they may have arising from the participant information sheet.

The procedure for taking informed consent from volunteer PR-buddies is described in Section 3.1.2.

DBS checks will be arranged by King's College London and there will be no cost to the site for this service.10.1.4 Recruitment of patient-participants

The steps in the recruitment of patient-participants are summarised in table 10.3 below.

Table 10.3 Stages in recruitment of patient-participants for PR-buddies to support.

Step towards recruitment of patient participant	To be done by
(Optional) Send a PR appointment letter with an IMPROVE short information sheet to COPD patients being offered pre-PR assessment (n=125 – 150 initially).	Designated PR staff
Phone COPD patients before date of pre-PR assessment, ask about interest in research, and complete screen for eligibility. If short information sheet was sent, check if patient saw short information sheet, re-send if required.. PR staff to collect verbal assent from interested patient-participants for their contact details to be passed to local CRN staff, research nurse, or research team.	Designated PR staff
Pass contact details for patients interested in taking part in IMPROVE trial to local Clinical Research Network (CRN) staff, local research nurse or research team.	Designated PR staff
Send detailed participant information sheet (PIS) to interested COPD patients.	CRN or Trust research staff
Follow up call to interested patients to answer questions after reading PIS.	CRN or Trust research staff
Complete consent meeting for interested patients (in person or remotely if preferred).	CRN or Trust research staff
If less than 36 people express interest in taking part in the trial repeat the process of recruitment from first step above with further 50 newly referred patients.	

The eligibility criteria and exclusion criteria for patient-participants are listed in detail in Sections 9.2 and 9.3. The recruitment of suitable patient-participants will be the responsibility of the staff from the PR team trained to work on implementation of the IMPROVE trial (designated PR staff) and staff from the local Clinical Research Network (CRN). Some NHS Trusts will also have research staff available to help clinical teams with recruitment of research participants. The designated PR staff will liaise with CRN staff and/or research staff (if available) to ensure logging of all the stages of recruitment of patient-participants including how many people they provide with the short information sheet; how many are contacted by phone; how many have consent meetings in-person; and how many are consented remotely. These logs will be stored in the site file and data will be shared with the central IMPROVE trial research team.

The designated PR staff will already have received training relating to recruitment of patient-participants. Designated PR staff from the direct care team may send IMPROVE short information sheets with PR appointment letters for COPD patients being offered pre-PR assessment (n = 125 - 150). Designated PR staff will follow-up these COPD patients to check if they saw the IMPROVE short information sheet (if sent); our experience in the feasibility study was that information sent by post is often missed by patients. The short information sheet will be re-sent if required. Calls will take place sufficient time prior to the date of the pre-PR assessment appointment to allow sufficient time for the recruitment process. Designated PR staff will ask patients about their interest in participating; complete a screen for eligibility; and obtain verbal agreement for their contact details to be passed to the Clinical Research Network (CRN) or Trust research staff identified as able to help with recruitment.

The central IMPROVE trial research team will provide a briefing for CRN staff and/or Trust research staff identified as able to help with recruitment by telephone or video meeting. These staff will complete recruitment and be responsible for taking consent from patient-participants (Section 10.3.3).

Trial sites will be randomised at, or soon after, their site initiation visit. Designated PR staff will be aware of which arm of the trial their site is in but must not reveal the allocation to potential patient-participants, to CRN staff or to Trust research staff involved with recruitment. These staff should be blind to the allocation of the site to intervention or usual care until after patient-participant recruitment has been completed (Section 10.1.4.2, Section 10.4, Section 10.5).

10.1.4.2 Blinding at consent of patient-participants

IMPROVE is an open, pragmatic, cluster randomised controlled clinical trial. Randomisation will occur at trial site level. Sites will be randomised at, or soon after, their site initiation visit; the PR team including the designated PR staff will not be blinded and will therefore be aware of the arm of the trial to which their site has been allocated. Potential patient-participants will be blind to the allocation of the PR centre to which they have been referred prior to giving informed consent. CRN staff, Trust research staff (and research assistants where required) who will take informed consent from patient-participants will be blinded to the arm of the trial of the local PR service. Further details relating to blinding can be found in section 10.5 below. More details of the consent process can be found in section 10.3.3 below. The designated PR staff will pass the contact details for patients interested in taking part in the trial to local CRN staff, Trust research staff (and central research team research assistants where required to provide additional capacity for consent meetings), taking care not to indicate the site's allocation.

The four categories of trial participants will be dealt with separately in this section.

10.2. Screening and eligibility

10.2.1 Trial Sites

The steps in the recruitment of sites are detailed in section 10.1.1. above. Screening of the stated eligibility criteria will be completed using the information provided by the PR service in the Expression of Intertest form. The IMPROVE Trial Manager will liaise with the PR site's local Clinical Research Network regarding site capacity and capability assessment.

Protocol waivers in relation to the Screening and Eligibility Assessment for site recruitment are not permitted. Rescreening of sites against eligibility criteria will only be permitted where the sites can provide evidence for a change in circumstances within the recruitment period for sites.

10.2.2 Individual PR staff at trial sites (sites randomised to the intervention arm)

Once the outcome of randomisation for the site is known the 3 staff in intervention sites nominated to be the designated staff will be screened for eligibility against the criteria detailed in sections 9.2 and 9.3. The screening will be completed by the member of the research team who completed the SIV and may take place on the same day as the SIV.

Basic demographic information (names and status within the service (job title and NHS employment band)) will be collected in a delegation log. PR staff data will not be used in process or outcome evaluation.

Protocol waivers in relation to the Screening and Eligibility Assessment for individual PR-staff recruitment are not permitted. Rescreening of staff against eligibility criteria will be permitted where a member of staff has withdrawn and will be replaced.

10.2.3 Volunteer lay health workers (referred to as PR-buddies)

The stages in recruitment and selection of volunteer PR-buddies are shown in table 10.2 and described in section 10.1.3 above. Screening and Eligibility Assessment of volunteer PR-buddies will be the responsibility of any or all of the 3 recruited staff in intervention sites. An initial Screening and Eligibility Assessment will be completed in phone calls to all interested individuals. PR-staff will also complete in-person selection interviews with volunteers which will also form part of their assessment for the individual's suitability to be recruited for participation in the trial as a PR-buddy.

Demographic information will be collected as part of the PR-buddy application process.

Protocol waivers in relation to the Screening and Eligibility Assessment for individuals volunteering for the PR-buddy will not be permitted. Rescreening of individuals if they are not deemed suitable to be offered a place on the PR-training at the selection interview will not be permitted.

10.2.4 Patient-participants

The stages in recruitment and selection of patient-participants for PR-buddies to support are shown in table 10.3 (consent) and described in section 10.1.4 above. Screening and Eligibility Assessment for patient-participants will be completed by local Clinical Research Network (CRN) staff or Trust research staff where available. Screening for eligibility will be completed and double checked in consent meetings for patients which will be in person at a convenient location for the patients (anticipated to often be at their home address), or remotely if preferred by the participant.

Protocol waivers in relation to the Screening and Eligibility Assessment for individual patient-participants will not be permitted. Rescreening of individuals if they are not deemed suitable will not be permitted unless there is evidence that information was incorrectly presented in the first place.

10.3. Informed Consent

10.3.1 PR-staff at trial sites (intervention arm)

Pulmonary rehabilitation staff who are identified as suitable and express a wish to take part in this trial as the designated staff in a PR-service in the intervention arm of the trial will be addressed as research participants in their own right. These staff will have a treatment role with patient-participants, and they will be identifying patients in their care for participation in the research. They will also be research participants in delivering the intervention, and they will be observed and assessed in that role. The member(s) of the research team completing the site initiation visit (SIV) will take written informed consent using the latest approved version of the Informed Consent Form (ICF). This may take place on the same day as the SIV or be done remotely working to an approved system for taking remote consent.

10.3.2 PR-buddy Volunteers

A copy of the latest approved version of the PIS for PR-buddies will be sent to volunteers who are offered a place on the PR-buddy training following a selection interview..

The site PI or one of the designated PR staff will take written informed consent from trainee PR-buddies using the latest approved version of the ICF during the first day of PR-buddy training after they have had

an opportunity to ask any questions that they may have. If any volunteers want longer to decide or want to speak to a member of the research team this will be arranged between day 1 and day 2 of the PR-buddy training. A copy of the signed ICF will be given to the participant. The original signed form will be retained at the trial site in the site file.

All PR-buddy participants will be asked at recruitment into the study if they consent to later invitation to take part in a possible interview or a focus group as part of the trial process evaluation. Individual in-depth qualitative interviews will be sought with any PR-buddies who drop out of the trial after completion of the training. Focus groups with PR-buddies at a sample of trial sites will be completed to investigate the acceptability of the intervention to PR-buddies as part of the process evaluation.

10.3.3 Patient-participants

CRN staff or Trust research staff will contact potential participants to arrange a consent meeting in-person (at the patient's home for their convenience) or remotely (by phone or video call) depending on individual patient-participant preference. If the participant agrees for the consent procedure to take place in-person, then they should provide written consent by signing the consent form and the researcher taking consent will co-sign the consent form shortly afterwards. If the participant would prefer to provide written consent remotely, then they should be sent a copy of the consent form, a cover letter and a self-addressed envelope in advance of the phone/video call. In the phone/video call, the researcher taking consent will go through the consent process with the participant and ask them to sign the consent form and send it back to the researcher if they are happy to do so. Upon receipt of the signed consent form, the same researcher who had gone through the consent procedure with the participant should sign the consent form and then send that participant a copy of the consent form with both signatures on it.

CRN field workers completing in-person consent meetings have long experience and detailed protocols for lone working. In regions where CRN staff or Trust research staff do not have capacity to complete the required number of consent meetings in a timely way, they will be assisted by appropriately trained research assistants from the research team.

The consent meeting will be an opportunity to go through the latest approved version of the Participant Information Sheet for patient-participants which will already have been sent to the patient.. Potential patient-participants will be asked to consent to participation without being aware if they will receive PR-buddy support or 'care as usual' when they start their PR.

A copy of the signed ICF will be given to the participant. The person taking consent will be responsible for ensuring the original signed ICF is taken in person, sent to the PR-staff or sent by secure mail or email to be retained in the site file. If the patient meets the study criteria, but wants more time to consider participation, a follow-up appointment will be made to take consent.

10.4. Randomisation

10.4.1 Trial Sites

Sites will be randomised to either the intervention or usual care. Allocation will be in the ratio 1:1, intervention:usual care. This is an open trial so allocation of sites will not be concealed from participating sites at the time of randomisation. Randomisation will be carried out remotely online at a central computer held by the King's Clinical Trials Unit (CTU). The research team will have access to the software

from the CTU. The trial is 'open cluster randomised', and PR site staff will not be blinded to the outcome. A member of the research team will document the outcome of randomisation in the TMF. Sites in the internal pilot will be randomised using fixed block sizes while sites in the main trial will be randomised using minimisation.

Minimisation will be used at site level, with a random element, to ensure that sites are well balanced between intervention and usual care arms at baseline.

Minimisation factors will be based on site characteristics:

a) If the service is stand-alone or embedded in another team
b) Type of PR programme delivery: rolling or cohort
c) Urban or rural service

In the event that the randomisation site cannot be accessed online at the time of randomisation, back-up telephone access will be provided by the King's Clinical Trials Unit.

10.5. Blinding

IMPROVE is a pragmatic, cluster randomised controlled clinical trial. Randomisation will occur at trial site level. Sites will be allocated at, or soon after, their site initiation visit.

Prior to consenting to participation potential patient-participants will be blind to the arm of the trial the PR centre to which they have been referred has been allocated. It is important that patient-participants do not know whether they will be offered the support of a PR-buddy when considering their decision about whether to take part. Without blinding to their allocation to intervention or usual care, patient-participants' agreement to take part in the trial may be influenced by whether or not they were going to receive the intervention, the support of a PR-buddy. This could lead to an imbalance between the two arms of the trial.

CRN staff, trust research staff (and central research team research assistants if they become involved in the consenting process) who will take informed consent from patient-participants will also be blinded to the arm of the trial to which the PR service has been allocated. More details of the consent process can be found in section 10.3. The designated PR staff will pass the contact details for patients interested in taking part in the trial to local CRN staff, Trust research staff, or research assistants involved in patient-participant recruitment, taking care not to indicate to them the arm of the trial to which the site has been allocated. None of the staff who will be taking consent from patient-participants will be based in the PR-service so should not be aware of the outcome of randomisation. Information relating to the status of sites in terms of which arm of the trial they are in will be held separately and confidentially by the trial manager. The central research team research assistants will not have access to information about the allocation of the sites in which they are recruiting patients.

It is not expected that un-blinding of the CRN staff, Trust researchers or central research assistants will occur at the patient recruitment and consent stage of this study. It is also not expected that there would be any reason, for participant safety or other reasons, for emergency un-blinding of these staff completing consent meetings.

Any instances of unintentional un-blinding of patient-participants at recruitment will be recorded.

10.6. Baseline Assessments

All baseline data collection and subsequent data collection have been detailed in section 8.4.

10.7. Withdrawal of Participants and Early Discontinuation of the trial

10.7.1 Withdrawal of Trial sites

A participating site may choose to withdraw from the trial at any time. Participating sites must agree to give at least four weeks' notice of their intention to withdraw from the trial. Such notice will give the trial team time to close the site and ensure all data have been collected and all formalities can be completed including informing all participants (patient participants and PR-buddies if appropriate). The date of withdrawal and reason for withdrawal will be recorded in the trial database.

It is intended that 38 sites (19 per arm) will be recruited to the trial. The design allows for the withdrawal of two sites without undermining the sample size calculation and the power to the trial to show a difference between intervention and usual care sites. In addition, although only two PR staff are required to run the intervention in intervention sites, each site is required to designate three members of staff as participants so that the integrity of the trial in that site will not be undermined if a member of the PR trial team has to withdraw due to leaving the service, illness, or maternity leave.

Closure of a site will be communicated to patient-participants individually by the participating site team. Patients who are still participating will be asked to continue to provide outcome data to the central research team, even though the intervention may come to an end prematurely. If a site giving notice of intention to withdraw is in the intervention side of the trial, arrangements will be made by the central research team to continue to manage and mentor PR-buddies if needed, and to support their withdrawal from their engagement with patient-participants. A management plan for the withdrawal of the site will be drawn up, taking into account local site circumstances and the position of PR-buddies (if the sites is an intervention sites) and patient-participants at that point in time. Implementation of the plan will be the responsibility of the Trial Manager supervised by the CI.

If a site withdraws from the study after PR-buddies have received their training, as long as they have had their first meeting (whether this is by phone or in person) with at least one patient-participant that had been assigned to them by the PR staff, they will still receive £90 for their time and reasonable travel/refreshment expenses will be reimbursed.

10.7.2 Withdrawal of Patient-participants

Study participants may withdraw from the study at any time and without any reason and this will be made clear in all participant study documentation. As per the consent form, data already collected from participants who wish to withdraw from the study will be used for the purposes of the trial.

The date of withdrawal and reason for withdrawal (if given) will be recorded in the trial database. If the participant has withdrawn due to an adverse event, the central research team will arrange for follow-up visits or telephone calls until the adverse event has resolved or stabilised.

10.7.3 Withdrawal of PR-buddies

Volunteer PR-buddies may withdraw from the study at any time and without any reason and this will be made clear in all participant study documentation. If a PR-buddy withdraws whilst part way through

supporting patients they will be asked if they feel able to continue to support these patients until the end of their PR. If the PR-buddy is not able or willing to do this the patients will be allocated to another PR-buddy at the same site.

Consent at entry into the study will include requesting that participants agree that if they decide to withdraw from the trial then all information collected up until that point can be used by the research team. If a PR-buddy withdraws early, confirmation will be sought that they still give this consent.

The date of withdrawal and reason for withdrawal (if given) will be recorded in the trial database. If the PR-buddy has withdrawn due to an adverse event, the research team will arrange for follow-up visits or telephone calls until the adverse event has resolved or stabilised.

Any PR-buddies that withdraw from the trial before the end of the intervention period will be approached to see if they will take part in a qualitative research interview to get feedback on their experience and explore the reasons they have withdrawn in order to obtain insight about the intervention from their perspective.

In the event that an intervention site withdraws from the study after PR-buddies had received training, the PR staff will arrange for the PR buddies to return their loaned mobile phones and the PR staff will make arrangements to send the loaned mobile phones back to the research team at King's College London.

10.8. Early Discontinuation of trial

Early discontinuation of the trial will be determined by the failure to achieve targets set for the internal pilot (Section 8.1).

The trial progression criteria will be based on

a) evidence of successful implementation of the intervention by PR service staff
b) evidence of successful recruitment and retention of PR-buddies and patient-participants
c) evidence that the trial integrity is not undermined by the COVID-19 pandemic.

The trial progression criteria and actions resulting are laid out in Table 10.4

Table 10.4 Progression criteria at the end of the Implementation-based Intervention Development (16 months)

Criteria to be assessed at 16 months	Proposed Action
a) Recruitment of 38 sites	Continue with trial
Recruitment of less than 34 sites	Review with ITSC

Recruitment of less than 30 sites	Consider stopping the trial
a) **Successful delivery of LHW intervention in each of two PR services:**	
8 LHWs recruited, trained and retained 2 patients per LHW supported	Continue with trial as planned
6 LHWs recruited, trained and retained 1 patient per LHW supported	Trial Steering Committee to discuss with the Trial Management Group and remedies to be applied urgently
4 LHWs recruited trained and retained < 2 patients per LHW supported	Discuss plans with Trial Steering Committee and NIHR HTA. Consider stopping trial
b) Obstruction of the trial by COVID-19	
None	Continue with trial as planned
Capacity of service reduced but still >75%	Continue with trial as planned
Capacity of service reduced by more than 25%	Trial Steering Committee to discuss with the Trial Management Group and remedies to be applied urgently
Unable to recruit and retain 6 LHWS due to social distancing	Discuss plans with Trial Steering Committee and NIHR HTA. Consider stopping trial

The evidence will be presented to the Independent Trial Steering Committee (ITSC) at the end of the internal pilot (Month 17).

Upon being informed by the ITSC of their decision, a substantial amendment will be submitted to reflect their decision and the co-sponsors will be informed of their decision.

Outside of not meeting the progression criteria for the internal pilot, the trial may be prematurely discontinued by the Sponsor, Chief Investigator, ethics committee concerned or Regulatory Authority on the basis of new safety information. If the trial is prematurely discontinued, active participants will be informed and no further participant data will be collected. The relevant Research Ethics Committee, the CI and the co-sponsors will be informed within 15 days of the early termination of the trial.

10.9. Definition of End of Trial

The end of trial will be the point at which all the data has been entered into the trial database, analysed and all queries resolved. The end of the study will be declared to the appropriate Research Ethics

Committee within 90 days of the study ending and all contact person(s) for each site in the study (along with the ITSC, stakeholder group and TMG) will be notified. A final report will be submitted to the same Research Ethics Committee within 12 months of the end of the trial.

10.10. Blinding and code-breaking

The IMPROVE trial is an open, pragmatic, cluster randomised controlled clinical trial. Blinding of participants will not be required after consent has been given. Blinding of recruitment staff (CRN teams, Trust research staff, and central research assistants) will have no consequence for the safety of patient-participants. Notes will be made of the occurrence of unblinding of patient-participants at recruitment and staff involved in consenting patient-participants.

11. TRIAL INTERVENTIONS

11.1. Theoretical framework

The theoretical frameworks underpinning the IMPROVE trial are important to understanding the structure and process of the intervention. They will also inform the process evaluation in this trial. The COM-B model of behaviour,(44, 45) in conjunction with Michie's behaviour change wheel will be employed to identify what needs to change in order for a behaviour change intervention to be effective, (35) and the Theoretical Framework of Acceptability,(46) will help to enable thorough investigation of all elements of intervention acceptability.

As stated previously the benefits of Pulmonary Rehabilitation (PR) are limited by poor uptake and completion. The reasons people don't go to PR are well documented and include travel issues, low mood, uncertainty about its benefits, and shame about still smoking. The COM-B model is based on elements that may either impede or facilitate behaviour that need to be considered when supporting behavioural change: Capability, Opportunity, and Motivation. Michie's behaviour change wheel provides a framework, which incorporates the COM-B model, to help characterise behaviour change interventions and support the development of more efficient behaviour change models. This framework will be used to inform the training for the IMPROVE intervention to enable the PR-buddies to use a structured approach to identifying the obstacles associated with attendance at PR and practical methods to support patients to overcome these obstacles.

Based on the known obstacles to completion of PR, targeted behaviour change techniques (BCTs) have been selected from the comprehensive behaviour change taxonomy.(47) The BCTs are described as targeted because a small number of relevant BCTs will be used which require minimum training and mirror the beliefs and experience of the PR-buddies and our PPI group members. An example of targeting is 'patients' low expectations of usefulness of PR'. With training the LHW can use their own experience and that of others known to them to demonstrate the potential effectiveness of PR for the patient. The known obstacles to attendance at PR have been mapped to these BCTs, to inform the training module for the volunteer PR-buddies on practical ways to overcome these obstacles. Table 11.1 highlights the BCTs selected from the behaviour change taxonomy, separated into the three components of the COM-B model, to indicate the obstacles to attending PR and how the BCTs can support the practical advice to overcoming these obstacles. In the training of designated PR staff in the sites randomised to the intervention arm of

the trial a comprehensive explanation of the theoretical framework underpinning the trial will be included. However, following advice from our patient and public involvement group the BCT's will be presented to the PR buddies as 'effective ways to help' for ease of understanding.

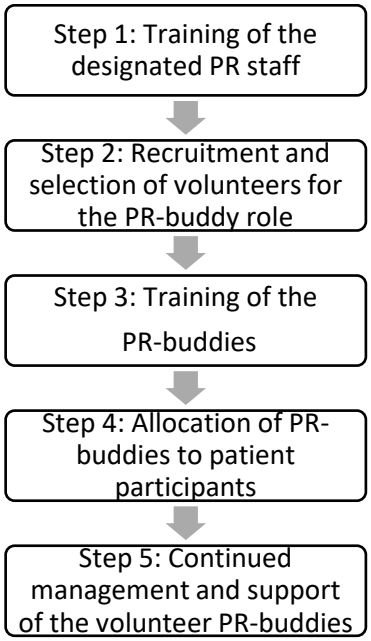
Table 11.1 Obstacles to attending PR and how behaviour change techniques can help.

Obstacle to attending PR	Behaviour Change Technique (BCT)	How the effective way to help (BCT) can be used to help
Motivation		
Low confidence in attending	Social support (practical & emotional)	Social support
Unsure about the benefits of PR	Information about health consequences (emotional consequences)	Information about the benefits of PR and how it is important for you
	Salience of consequences	
	Pros and cons	Discuss pros and cons if appropriate. How the PR-buddy benefited from PR and discuss difficulties at the beginning and how things improved. Reassurance it is appropriate for their fitness level.
	Comparative imagining of future outcomes	
	Vicarious reinforcement	
Capability		
Does not know where the classes are Does not have appropriate clothing for PR class	Instructions on how to perform behaviour	Information on where the classes are and reassure that specialist clothing is not required.
Unsure what they want to achieve from PR	Goal setting (behaviour)	Action planning/prompts and cues. PR-buddy could be the prompt/cue (for example ringing on morning of PR class) or advice on setting a phone reminder.
	Goal setting (outcome)	
Forget that the class is happening	Action planning	
	Prompt/cues	
Opportunity		
Struggling to prioritise attending PR	Social reward/self-incentive	Praise from PR-buddy or family member when they do attend PR. Reward self when they do attend.
Unsure of how to get to PR session Cannot find time in their week to attend	Problem solving	Resolving issues that may prevent them attending PR (i.e., route planning to get to PR). Discuss how if they miss other activities to make time to attend PR how they might benefit in the long run
	Restructuring physical/social environment?	

11.2. IMPROVE Intervention

The intervention can be summarised as setting up and running a PR-buddy service. This involves a five-step process. The trial will use a 'train the trainer' method. PR staff in services randomised to the intervention arm of the trial will be trained by the research team. The training is detailed below but will include how to recruit and select volunteer PR-buddies from those who have recently completed PR in their PR service. The PR staff will then deliver the PR-buddy training and manage and support the PR-buddies throughout the intervention. The steps are described in more detail below and shown in figure 11.1

Figure 11.1 Five steps in the IMPROVE intervention.



11.2.1 Training of the designated PR staff

The training for PR staff will be delivered by Dr Gill Gilworth (Senior Research Fellow) and Dr Kate Harris (Health Psychology Research Associate). It has been designed in collaboration with Dr Emma Godfrey (Health Psychologist) and Dr Arietta Spinou (Respiratory Physiotherapist); these 4 people have formed a training development group. Godfrey has established research experience in delivering training in the use of behaviour change techniques to physiotherapists, (NIHR PB-PG-1112-29055 and NIHR HTA15/165/04).

Each intervention site will have 3 designated PR staff members who will receive the training. At least two staff members will be trained health care professionals (for example physiotherapist, respiratory nurse, occupational therapist). The additional staff member will have at least one year's experience of working in the PR team (for example physiotherapy assistant)'. The training for PR staff will be 2 ½ days. Following consultation with our stakeholder group delivery will be a mixture of face-to-face and 'remote live' training using a video platform and a ½ day self-directed learning.

An overview of the training can be found in the table below. Across the three days, the training for the PR teams will include modules on the IMPROVE trial background and methodology; the theoretical basis; research systems and record keeping; recruitment and selection of volunteers to train as PR-buddies, training of PR-buddies (including the role of the PR-buddy, effective communication, boundaries, obstacles to PR attendance and how to overcome them using behaviour change techniques); ongoing running of the PR-buddy service including the management and support of the volunteers. The training will also include an assessment, in the form of a training review, at the end of day three. Table 11.2 below gives an overview of each day of the training.

The PR-staff training will be interactive, with training videos and practical sessions throughout to allow the teams to practice what they have learned. A training manual will be designed by the IMPROVE training development group for the delivery of the training to the PR staff. This manual will include the training programme, templates to log progress for record keeping throughout the intervention period, exercises and assessment methods used in the formal training. It will be available for the PR teams to refer to as they set up the PR-buddy service and will also be available for subsequent implementation of the intervention within the NHS if the trial is successful.

Table 11.2 PR Staff training: outline of course programme

Day 1 – ½ day on-line self-directed learning	Components
The IMPROVE trial background and methodology	• Introduction to training course and manual (for PR-staff) • Introduction to the trial: What is the problem being addressed? • Background and methods, the feasibility study key findings (training video) • The stages in the intervention: steps to setting up a PR-buddy service • Key responsibilities (PR team and PR-buddies) • Research systems and record keeping • Theoretical framework (an introduction)
Day 2 (remote live full-day session)	Introductions and ice breaker Recap of ½ day on-line self-directed learning
Volunteer recruitment and selection	• Volunteer recruitment and selection: eligibility criteria for potential PR-buddies • the PR-buddy role, required skills and experience • The recruitment process • Selection interviews • The volunteer agreement • DBS checks and taking informed consent
Putting theory into practice	Mock volunteer interviews. Putting the selection process into practice
Theoretical basis of the trial: barriers to PR and behaviour change techniques (BCTs)	• Barriers to PR uptake and completion – what we already know • Selection of BCTs to be used and presentation to PR-buddies as 'effective ways to help'

PR-buddy training 1	Practicalities: preparations • getting the venue right • resources: introduction to PR-buddy training manual and PR-buddy working files • Volunteer agreements and occupational health forms
The PR-buddy role	The PR-buddy role in practice: boundary setting and confidentiality
PR-buddy training 2	• communication skills • telephone technique • PR-buddy logs and record keeping
RE-cap of the day and question and answer session **Group discussion (to be used as part of assessment of fidelity of receipt of training)**	
Day 3 (face-to-face group session)	Introductions and ice breaker Recap of day 2
PR-buddy training 3	• Re-cap of Theoretical framework: Behaviour Change (training video) • Techniques (BCTs) and the COM-B framework • Application of BCTs and mapping to barriers to PR • Rationale for chosen techniques • Lay terminology and presentation to PR-buddies
Putting theory into practice	Putting BCT training into practice Teaching of communication skills, confidentiality and use of BCTs
PR-buddy management and support	• Place of PR-buddy supervision and peer support in the intervention • Determining the need for refreshment of PR-buddy skills • Ongoing record keeping and downloading of data from PR-buddies phones
Recruitment of patient-participants	• identifying potential patient-participants the role of the CRN and/ or Trust research staff • inclusion criteria for patient-participants • supporting documentation
Assessment	Assessment by training review
RE-cap of the day and question and answer session	

11.2.2 Recruitment and selection of volunteers for the PR-buddy role

The procedure for the recruitment of volunteers interested in the PR-buddy role is described in detail at section 10. The first part of the recruitment process will involve identifying patients from the PR service who have COPD and who have previously completed PR themselves. Potential volunteers will be invited to take part in the trial a brief information sheet will be provided initially. Follow-ups will then be made to those who have expressed an interest to answer any questions they may have. Screening for eligibility will be completed and a decision will be made on whether to offer a selection interview. Suitable volunteers meeting the eligibility criteria will be sent an application form and training information sheet. The designated PR-staff will receive training on how to recruit and select who to offer training places to

from the people who volunteer during their training. All the PR sites will use the same selection criteria which included appraisal of the written application form and an in-person interview. Each site will be aiming to interview between 12 and 16 volunteers.

Following the selection interviews, letters to invite suitable interviewees to PR-buddy training will be sent, with a target of 6-12 volunteers to be offered a training place. Volunteers offered a training place will be sent the full participant information sheet and a copy of the volunteer agreement. Potential PR-buddies will be consented, and the volunteer agreement will be signed on day 1 of the PR-buddy training. Ideally, the identity checks will also be completed at day one of PR-buddy training but this can be done on another day if necessary.
If successful volunteers do not confirm that they will be taking up a training place, the PR teams will contact them to confirm their attendance.

11.2.3 Training of PR-buddies

Training for PR buddies will be delivered in person to a group of around 6-12 volunteers. Training will be three days one day of training per week for 3 consecutive weeks). The training will be delivered by two members of the PR team who previously attended the PR staff training. The training will include the role of a PR-buddy communication skills, and the use of behaviour change techniques to overcome barriers to attendance at PR. The PR buddies will be taught about the relevant BCTs, which will be presented as 'effective ways to help' The PR-buddies will be encouraged to use their own experience of attending PR to overcome some of the obstacles regarding the effectiveness of PR. Throughout the training days, there will be opportunities for the PR-buddies to put into practice what they have learned, through role plays and group discussions.

Figure 11.3 Outline of training programme for the PR-buddies

Aim	Sessions
Day 1	
To provide an overview of the IMPROVE trial To understand how personal experiences of COPD and PR can support others	Session 1: Welcome and housekeeping The IMPROVE trial and the role of PR-buddies Session 2: The role of being a PR-buddy Understanding boundaries of being a PR-buddy The importance of confidentiality Lunch break Session 3: Example of an effective conversation Questioning style Break Session 4: Having an effective conversation Putting into practice Questions and close
Day 2	

To look more closely at the barriers to attending PR and to look at ways to reduce these barriers and support patients to attend PR	Session 1: Recap from day 1 Overview of the barriers to PR Break Session 2: How you can help part 1 Lunch break Session 3: How you can help part 2 Break Session 4: Putting into practice – training video and group discussion (observed and assessed by staff) Questions and close
Day 3	
To look at the boundaries involved in being a PR-buddy Record keeping The support expected from PR teams	Session 1: Welcome and housekeeping Recap from day 2 Summary of the intervention Break Session 2: Practical support for phone use Group activity Lunch Session 3: Boundaries and confidentiality Break Session 4: Record keeping Support Course review/ quiz Questions and close

The group discussion at the end of day 2 and course review/ quiz at the end of day 3 will be used to assess fidelity of receipt of training by PR-buddies. Any PR buddies who do not successfully pass these assessments and are therefore not sufficiently prepared to support patients in the PR-buddy role will be offered further training or signposted to alternative volunteering opportunities that might be more suitable for them.

11.2.4 Allocation of PR-buddies to patient-participants

The PR services will be responsible for allocating PR-buddies to patient-participants. All patient-participants being offered a place to start PR will be made aware of the PR-buddy service and given the opportunity to take part in the research during the period of recruitment of patient-participants. As part of giving consent to participation patients will provide their consent for the PR teams to share their

contact details with the PR-buddies. More information on how the PR-buddies and patient participants will be recruited can be found in section 10 of this protocol.

The PR-buddies will be lent a phone to use to contact patients so that they can keep their personal contact details private. The frequency of the support and the method of contact (face-to-face or via phone) will be agreed between patients and PR-buddies and will vary depending on the level of support the patient-participants needs. All contact between the PR-buddy and the patient-participants will be recorded by the PR-buddy, to protect the interests of both. A random sample of the recordings will be used to assess the fidelity of the intervention and the service delivery. The PR team will ensure that the number of patients supported by a single PR-buddy at any one time is reasonable and appropriate for the capacity of the PR-buddy. It is expected that each individual PR-buddy will not support more than three patients concurrently.

11.2.5 Continued management and support of the volunteer PR-buddies

The PR team will be responsible for ensuring that the PR-buddies receive ongoing support during their volunteering. The PR-buddies will have monthly group meetings with the PR teams to discuss any issues, address concerns and for peer support. The PR team will also use these meetings to ensure that the workload for each PR-buddy is acceptable and that they are having contact with their patient-participants. The meetings may also be used to reinforce elements of the PR-buddy training. PR-buddies will also have the contact details for the PR team and the research team for any urgent queries or concerns.

Details about selection and withdrawal of subjects can be found in sections 9 and 10.1.

12. SAFETY REPORTING

12.1. Safety considerations

We do not foresee any significant risks or burdens for the research participants (patient-participants, PRBs and PR staff) in this study. We will be aware of the risk of psychological distress for patient-participants and for PRBs. Pulmonary rehabilitation itself is a low-risk treatment as is evident from a recent systematic review of sixteen trials of pulmonary rehabilitation in patients undergoing an acute exacerbation.(11) In only four trials were adverse events reported. Three patients suffered ‘more serious’ adverse events, all of which were due to underlying co-morbidities. The intervention under examination in this trial is one of communication between trained PR-buddies and patients with COPD referred for pulmonary rehabilitation. No adverse events were reported in the feasibility study. The opportunity for the intervention to lead to harm to patient-participants or the PR-buddies themselves seems minimal. The minimisation of risks and burden on the patient participants including to carers and to professionals is explained below. Risk to researchers visiting patients’ homes or to PRBs meeting patient-participants by phone or in person has been addressed in our adoption of the King’s College London fieldwork guidelines, particularly the guidance on lone-worker risk prevention (which follows the guidance outlined in https://www.nhsemployers.org/sites/default/files/media/HSWPG-Lone-Workers-staff-guide-210218-FINAL_0.pdf). PR-buddy training will include the boundaries of the role. It will be emphasised that PR-buddies should only agree to meet patients in public places such as cafés.

Managing volunteers requires clear processes and lines of communication especially in relation to the participants with whom they will be interacting. We have established a detailed but clear agreement or charter which lays out roles and responsibilities of both the volunteers and the institutions in which they

will be based. Confirmation of identity and Disclosure and Barring Service checks will be a high priority. The use of smart phones to record all interactions is an essential element of the LHWs' and the participants' security. Our research team will be conducting visits to sites and to patients. Close adherence to our lone worker protocols will be carefully monitored by the trial manager, as well as the conduct of risk-based monitoring remotely, as appropriate to check that all procedures and being followed, ensuring patient safety. Researchers will have personal details for the participants they will be visiting so we will have a protocol for ensuring that those details are protected securely.

The Site PIs, or the medically qualified delegated team member for the study site, will assess adverse events (AE) or adverse reactions (AR) to establish if they should be classified as Serious AEs (SAE). They will report the AE and their deliberations to the CI. AEs will be reported by the patient to a member of the PR-staff. The research team will contact all sites at the midway point and end of the trial to collect AEs. Any SAEs will be reported to the research team by the PI as soon as they are aware of it. All harms data will be considered by the Trial Steering Committee (TSC). Procedures for reporting AEs will follow the guidance of the HRA (https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/safety-and-progress-reports-other-research-procedural-table/).

If an AE is not defined as serious, the AE will be recorded in the study Case Report Form (CRF), and the participant will be followed up by the research team. The AE will be documented in the participants' medical notes (as per site protocols) where appropriate.

An SAE occurring to a research participant will be reported to the Chair of the study ITSC (as part of the routine report produced to TSC) and in the participant's medical notes (as per site protocols), where in the opinion of the CI the event was:

- Related – that is, it resulted from administration of any of the research procedures
- Unexpected – that is, the type of event is not listed in the protocol as an expected occurrence.

SAEs that are considered to be 'related' and 'unexpected' will be reported to the sponsor within 24 hours of learning of the event and to the main REC within 15 days in line with the required timeframe (https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/) .

A safety form will be completed for each SAE and will be signed by the CI or appropriate staff before forwarding the scanned copy to sponsor.

The definitions of adverse events are given in Table 12.1. For the purpose of adverse event reporting, the "IMPROVE intervention" consists of contact with PRBs and participation in pulmonary rehabilitation.

Table 12.1 Definitions of Adverse Events

Adverse Event (AE)	Any unfavourable and unintended occurrence in a participant participating in the IMPROVE trial including occurrences that are not necessarily caused by or related to the intervention.
Adverse Reaction (AR)	An untoward and unintended response in a participant to the IMPROVE intervention that is related to the intervention.

	The phrase "response to the intervention" means that a causal relationship between the intervention and an AE is at least a reasonable possibility. All cases judged by either the reporting clinically qualified professional or the Sponsor as having a reasonable suspected causal relationship to the IMPROVE intervention.
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • results in a congenital anomaly or birth defect Other 'important medical events' may also be considered a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
Serious Adverse Reaction (SAR)	An adverse event that is both serious and, in the opinion of the reporting Investigator, believed with reasonable probability to be due to the IMPROVE intervention.

12.2. Events exempt from reporting as SAEs

Expected adverse events may include musculoskeletal events, falls, and anxiety or other psychological distress related to attendance at PR or contact with the PRB.

Hospitalisation for a pre-existing condition, including elective procedures planned prior to study entry, which has not worsened, does not constitute an SAE. Standard supportive care for COPD does not constitute an SAE. Hospitalisation or attendance at the emergency department for COPD, that the site PI described as related to the IMPROVE intervention, should be classed as a SUSAR.

The safety reporting window for the trial will begin at the time of consent and will end at the completion of pulmonary rehabilitation. Adverse events will be followed up until event resolution or stabilisation or until completion of the trial whichever occurs first.

12.3. Assessment of Causality

The relationship of each adverse event to the IMPROVE intervention must be determined by the Site PI according to the following definitions:

Related: The adverse event follows a reasonable temporal sequence from participating in the IMPROVE intervention. It cannot reasonably be attributed to any other cause. Events can be assessed as definitely, likely or possibly related to the study intervention.

Not Related: The adverse event is probably produced by the participant's prior clinical state or by other intervention or events not related to IMPROVE. Events can be assessed as either unlikely or not related to the study intervention.

12.4. Procedure for immediate reporting of Serious Adverse Events

Taking into account the rare reporting of adverse events in previous trials of pulmonary rehabilitation, all sites will be provided with and instructed in the procedure for reporting severe adverse events. The procedure will follow a process as follows:

in the event of an SAE:

- Site study team will complete an SAE report form for all reportable SAEs.
- Where the SAE requires immediate reporting, the SAE report form will be scanned and emailed to the IMPROVE trial manager (toby.morgan@kcl.ac.uk) immediately i.e., within 24 hours of site study team becoming aware of the event.
- Site study team will provide additional, missing or follow up information in a timely fashion.

Receipt of the SAE report will be recorded at the time of the receipt and acknowledged. A CRF form will be completed and uploaded. The SAE will be reported to the sponsor's office (sent to R&D@gstt.nhs.uk), acknowledgement of receipt will be recorded, and review will be recorded on receipt.

The assessment of expectedness will be completed at the reporting site by the local PI. The trial's SAE form and completion guidelines will be designed with King's Clinical Trials Office at the time of commissioning the trial database and will reflect the SAE and its expectedness.

All SAEs, other than those defined in the protocol as not requiring reporting, must be reported on the SAE reporting form to the sponsor (GSTT/R&D) within 24 hours of the IMPROVE trial team becoming aware of the event. SAEs that are reported late will be accompanied by an explanation for this. In all respects the trial team will follow the sponsors SOPs with respect to SAEs

13. STATISTICS and HEALTH ECONOMICS

13.1. Overview

The statistical and health economic aspects of the trial are summarised here. Statistical details will be fully described in a statistical analysis plan (SAP) that will be available in a separate document from the time that the first site is recruited. The plan for the statistical analysis of the trial is outlined below in Section 13.2.

Health economic details will be fully described in a health economic analysis plan (HEAP). An outline is written below (Section 13. 3).

13.2. Description of Statistical Methods

The trial is an open pragmatic cluster randomised controlled clinical trial. The primary outcome is completion of PR (yes/no) by each individual patient-participant summarised as a proportion for each cluster site. PR completion is defined as attendance at 70% or more of planned PR classes, usually at least 8 of 12 classes. Patient-participants who achieve this attendance rate but fail to attend the final assessment class will be contacted by a researcher to carry out the final assessments. Sample size is based on an absolute rise of at least 16% (relative increase 40%) in intervention sites compared to usual care in control sites. Secondary outcomes are:

(i) PR site rates of improvement, at minimal clinically important differences or greater, in exercise capacity, symptoms, respiratory-specific quality of life and generic quality of life (EQ5D5L).

(ii) Rates of attendance at PR assessment (uptake)

Randomisation and minimisation criteria have been described in section 10.3.1.

13.2.1 Sample size

Sample size has been estimated for a comparison of the proportion of participants who complete PR between intervention sites and control sites. Randomisation will be carried out at the level of PR centres. PR centres will form clusters about which the sample size has been generated. Participants will be unaware of the randomisation status of their PR service at the point of recruitment.

Based on the 2017 PR audit of the Royal College of Physicians (RCP), the mean completion proportion over all 182 pulmonary rehabilitation sites was 40%.(13, 48) Sites already achieving almost 40% more than average completion rates in England are likely both to have a much smaller margin of improvement available and a much-reduced opportunity for the intervention to show a difference. Sites with a completion proportion of 55% or less were considered “sub-optimal performers”. As some sites may not have data about the number of relevant referrals that complete PR, to aid recruitment of sites, sites that have a completion proportion of 65% or below for patients that attended the first assessment will also be included in the main trial. The mean completion proportion amongst sub-optimal performing sites was estimated at 32%. Due to regression to the mean, it is likely that these sub-optimal performing sites may perform better the following year, and so the control group completion proportion is likely to be somewhere between 32-40%.

Assuming an overall completion proportion of 40% in the control group, 36 sites (18 per arm) would be required to detect a 40% relative increase in completion proportion to 56% (i.e. a 16 percentage-point increase) with 90% power, assuming an ICC of 0.056 and 30 participants per site. Assuming a completion proportion of 32% the same number of sites would also be required to detect a 16 percentage-point increase from 32% to 48% (relative increase 50%) assuming the same power and ICC. Therefore, after accounting for one site per arm dropping out, a total of 38 sites (19 per arm) would be required. After accounting for six (20%) patients dropping out, 36 patients would be required in each site.

13.2.2 Analysis Populations

All sites randomised and allocated to the intervention or usual care side of the trial will be included in the analyses. All patient-participants recruited and giving informed consent will be included in the calculation of site uptake and completion rates. Pre-specified sensitivity analyses will be written into the Statistical Analysis Plan (SAP)

13.2.3 Stopping Rules – Internal Pilot

The purpose of the internal pilot in the IMPROVE trial is to ensure that the feasibility of recruiting and training and retaining PRBs is confirmed and that the impact of the COVID-19 pandemic has not led to unacceptable changes in the administration of pulmonary rehabilitation so that the trial cannot be conducted. The stop-go criteria have been laid out in in section 10.8.

13.2.4 Procedure for Accounting for Missing Data.

We will also perform sensitivity analyses to assess the robustness our results to various assumptions regarding missing data, or participants lost-to-follow-up: for this we will assess the feasibility of using a multiple imputation approach (depending on the entity and structure of missingness).

The procedures for addressing missing data and the conduct of sensitivity analysis to assess their impact will be described in detail in the Statistical Analysis Plan, along with procedures for reporting any deviations from the original statistical plan.

13.3. Health Economics Analysis

13.3.1 Rationale

COPD is the largest (29%) contributor to the costs of all respiratory diseases in the UK (49). In 2013-4, the direct costs of COPD amounted to £1,847million, the indirect cost £61million, and the intangible costs, assuming each disability-adjusted life year lost is valued at £20,000, were a further £15,545million (49).

Pulmonary rehabilitation (PR) may be cost-effective or cost-saving over the short term. Griffiths et al (2001) compared an 18-visit, 6-week PR programme to standard management in 200 patients.(41) They found PR to be cost saving (cheaper yet quality of life enhancing) and these data continue to be cited in the NICE guidelines.(50) The Griffiths, et al. (2001) study has not been repeated either in the UK or

elsewhere, and debate continues on the extent of hospital cost savings within a year. The health economic analysis of PR conducted in this trial will be the first for more than 20 years.

Four recent systematic reviews (51-54) of COPD treatments reported long-term models for pharmaceutical interventions. Of the models reported, two focused on the UK (55, 56). We will include relevant elements from these models in our trial.

13.3.2 Assessment

The within-trial economic evaluation, to be developed in accordance with good practice guidance (57, 58), will adopt the perspective of the NHS and Personal Social Services' perspective as well as that of the society. Intervention costs included will account for set up (e.g. PR staff training, recruitment and training of PRBs, DBS checks), and delivery activities (e.g. setting up appointments by mail and phone, phone/face-to face patient support, travel by PRBs to support patients, managing and support of PRBs by PR centres). Participants in both trial arms will be asked about their time and money costs associated with accessing and maintaining PR over the course of the trial, alongside their use of primary (e.g. attendance of PR, visits to GP, nurse, use of home oxygen) and secondary health services (visits to A&E, inpatient stays). Research-only costs (e.g. recruitment of sites) and further intervention development costs will be excluded as they are not relevant to estimating the costs of 'rollout'. Data will be collected using a mix of approaches including case report form (CRF), participant questionnaire, smart phone records, patient-level Information and costing system (PLICS), trial and routine administrative records, interviews with and records kept by key personnel (e.g. PRBs, PR centres) (see Section 8.4.8). We have developed a health resource use questionnaire using consultation with our PPI co-applicant and PPI group. To increase generalisability, resources will be valued using national unit prices e.g. national tariffs using PLICS methodology (59) or Healthcare Resource Group codes (where not available), or Personal Social Services Research Unit data.(60)

EQ-5D-5L QALYs will be calculated using an area under the curve approach (61) by mapping the EQ5D5L data to the EQ5D3L value set, as recommended by National Institute for Health & Care Excellence (NICE).(62, 63) We will follow the latest recommendation by NICE by the time of trial analyses, e.g., if an EQ-5D-5L value set becomes available.(64) QALYs and costs will be based on secondary outcome data collected in the trial, with cost data covering the entire period and EQ5D5L utilities collected at baseline, 3 months and 6 months.

Methods for analysing missing data will adopt practices recommended in current guidance.(65, 66) We will assess the impact of alternative strategies for missing value replacement in sensitivity analysis. In addition to the usual presentation of cost-effectiveness acceptability curves, and net benefit analysis, we will assess the impact of PR completion rate on the findings using: a) sub-group analysis, based on those who do and do not complete PR and those who complete 75% of PR sessions or not, with other percentages of PR completion rates tested in sensitivity analyses and b) an instrumental variable approach to determine whether a local average treatment effect or treatment effect is used (71). The choice of instrumental variable could account for other potential causal factors (e.g. age, gender, distance between services, genetics) with an 'average causal response' weighting function.(67-69)

If the PR intervention is effective at increasing PR completion rate, longer-term Markov-models of cost-effectiveness and budget impact will be developed. These will account for changing severity over time (e.g., by quality of life – CAT, exacerbations and death) with costs and utilities attached to each state. The budget impact model will additionally account for the current and expected size of population with COPD as well as disease severity. The models will provide analysis based on 1-, 3- and 5-year time horizons,

with the economic model extended to a life-time horizon if results for these time horizons are ambiguous and if the lifetime horizon has potential to be relevant and credible. Both models will be subject to sensitivity analyses e.g. alternative assumptions of exacerbations over time, varying the frequency of PR courses over a life-time, and varying the referral decision from Grade 2 to 3 MRC score. Modelling will adhere to good practice guidance,(70, 71) with details of all statistical and economic methods published in the trial protocol and analysis plan before investigators are unblinded to trial outcomes.

14. DATA MANAGEMENT

A detailed Data Management Plan (DMP) will be written to cover all aspects of managing the data including:

> CRF design, MACRO® (Elsevier) electronic data capture database for collected data, data entry, data handling processes including data checking, query management and cleaning, data transfer, quality control procedures, data storage, processes for interim and final data extractions, the procedures for freezing and locking the databases, and data archiving.

The DMP will be linked to the SAP and HEAP. The basis of the DMP for the study is outlined in Sections 14.1 – 14.2.1. Much of the plan is already included in other sections of this protocol document. These elements will be included in the formal DMP.

Data for analysis will be entered and stored in the Kings Clinical Trials Unit (KCTU)-managed MACRO® electronic capture software (Elsevier). KCTU standard operating procedures (SOPs) with regard to MACRO® will be adhered to by the study team.

The Data Management Plan will be compliant with GSTT (https://khpcto.co.uk/SOPs/18_DataSOP.php) and KCL guidelines and SOPs (https://www.kcl.ac.uk/researchsupport).

The flow of data between the research team and the PR sites is presented schematically in Appendix E.

MACRO EDC

A web based electronic data capture (EDC) system will be designed, using the InferMed Macro 4 system.

Data entry

The EDC will be created in collaboration with the trial analyst/s and the CI and maintained by the King's Clinical Trials Unit for the duration of the project. It will be hosted on a dedicated server within KCL.
Source data will be entered centrally by the co-ordinating study team, typically within 30 days of data collection by authorised staff onto the EDC by going to www.ctu.co.uk and clicking the link to access the MACRO 4 EDC system. A full audit trail of data entry and any subsequent changes to entered data will be automatically date and time stamped, alongside information about the user making the entry/changes within the system.

Security

The CI or delegate will request usernames and passwords from the KCTU. Database access will be strictly restricted through user-specific passwords to the authorised research team members. It is a legal requirement that passwords to the EDC are not shared, and that only those authorised to access the system are allowed to do so. If new staff members join the study, a user-specific username and password must be requested via the CI or delegate (e.g., Trial Manager) from the KCTU team and a request for access to be revoked must be requested when staff members leave the project. Study site staff experiencing

issues with system access or functionality should contact the CI or delegate (e.g., Trial Manager) in the first instance.

Participant initials and possibly date of birth will be entered on the EDC. Whereas NHS number, email addresses, participant names and addresses and full postcodes will not be entered into the EDC system. No data will be entered onto the EDC system unless a participant has signed a consent form to participate in the trial.

Data Quality Processes
The CI team will undertake appropriate reviews of the entered data, for the purpose of data cleaning and will request amendments as required.

The KCTU will provide the study team with Data management plan for Elsevier InferMed MACRO EDC once the system is made live and ready for use.

Database Lock
At the end of the trial, the site PI will review all the data for each participant and provide electronic sign-off to verify that all the data are complete and correct. At this point, all data can be formally locked for analysis.

Upon request, KCTU will provide a copy of the final exported dataset to the CI in .csv format and the CI will onward distribute as appropriate.

KCTU Randomisation

A web based randomisation system will be designed, using the bespoke KCTU randomisation system. The randomisation system will be created in collaboration with the trial analyst/s and the CI and maintained by the King's Clinical Trials Unit for the duration of the project. It will be hosted on a dedicated server within KCL.

Data entry
Randomisation will be undertaken centrally by the co-ordinating study team by authorised staff onto the randomisation system by going to www.ctu.co.uk and clicking the link to access the randomisation system. A full audit trail of data entry will be automatically date and time stamped, alongside information about the user making the entry within the system.

Security
The CI or delegate will request usernames and passwords from the KCTU. System access will be strictly restricted through user-specific passwords to the authorised research team members. It is a legal requirement that passwords to the randomisation system are not shared, and that only those authorised to access the system are allowed to do so. If new staff members join the study, a user-specific username and password must be requested via the CI or delegate (e.g., Trial Manager) from the KCTU team and a request for access to be revoked must be requested when staff members leave the project. Study site staff experiencing issues with system access or functionality should contact the CI or delegate (e.g., Trial Manager) in the first instance.

Participant initials and date of birth will be entered on the randomisation system. Whereas NHS number, email addresses, participant names and addresses and full postcodes will not be entered into the randomisation system. No data will be entered onto the randomisation system unless a participant has signed a consent form to participate in the trial.

Data Quality Processes
The CI team will undertake appropriate reviews of the entered data, for the purpose of data cleaning. No data can be amended in the system, however CI or delegate (e.g., Trial Manager) may request King's Clinical Trials Unit to add notes against individual subject entries to clarify data entry errors.

Database Lock
Upon request, KCTU will provide a copy of the final exported dataset to the CI in .csv format and the CI will onward distribute as appropriate.

14.1. Source Data

Source data for the trial will be based on the outcomes in Tables 8.1-8.4.

CRF entries will be considered source data if the CRF is the original record (e.g. there is no other written or electronic record of data).

14.1.1 CRF design

The CRFs for the trial will be designed with the KCTU and will follow their SOPs. All patient-participants will be assigned a unique study identifier (ID) which will be assigned at study entry for use on research documents. These numbers will be stored on a password protected file on a secure server at KCL. Questionnaires from which results will be entered in CRFs, will, where necessary, be licensed for use in the trial and will receive research governance and ethical approval.

Data collected on CRFs will include registration data; eligibility; research status recruited / completed / withdrawn; PR site details; COPD date of diagnosis, exacerbation record, co-morbidities; PR attendance record; CAT questionnaire; CRQ-SAS questionnaire; HADS questionnaire; MMRC questionnaire ; 6-minutes walking distance test; incremental shuttle walk test; EQ-5D-5L; health and social care resource use (questionnaire); acceptability; adverse reactions/events; withdrawal from the study.

14.1.2 Data management system, data storage and archiving

Quantitative data

Details about collection of quantitative data can be found in Section 8.4. Data will be entered onto electronic-CRFs on the KCTU MACRO® database following KCTU SOPS. Access to the MACRO® database will be made by available to the trial team staff only. PR sites will not have access to the MACRO® database.

Paper data will be kept in a secure locked filing cabinet at either King's College London, the University of Leeds or in the site file at a PR site. PR centres will be required to keep their IMPROVE site files in a locked filing cabinet or secure locked room. Access to trial documents should be restricted to only those who are delegated to work on the IMPROVE trial.

Participant contact details will be stored securely in a locked filing cabinet in a locked room, or on password protected computers and kept separately from the other data obtained.

Audio-recorded data

Audio-recorded data will be recordings of interactions between PRBs and patient-participants or recordings of individual qualitative interviews and of focus groups. Audio recorded data collected by PRBs will be transferred from the IMPROVE mobile phones and saved on computers with password protection before being uploaded to secure servers at KCL. Audio files will be transcribed by a third-party transcription service (Clear Voice Interpreters & Translation Limited), a known supplier to King's College London with an established method of secure transfer of recordings. Any identifiable information mentioned in the interview will be removed prior to sending the audio recordings to the transcription company.
Prior to transfer of data to the secure server, laptop computers containing data will be kept in a locked filing cabinet in a locked room.

The audio-recordings will be deleted from the phone and computer once the data is in the secure server. The transcripts will be saved on the secure server which will be accessible by the study researchers for analysis.

Record Retention and Archiving

KCL operates a research data repository, King's Open Research Data System (KORDS), based on the Figshare® data repository system. It provides a simple self-deposit way to upload data, providing long-term secure storage and access to datasets at project-end. Depositing meets the policy requirements of funders for data retention and sharing, and the requirements of many publishers for access to datasets supporting publications.

King's Open Research Data System supports Open Research, enabling researchers to make datasets discoverable, accessible and citeable. All datasets have a digital object identifier and a structured metadata record so that they can be shared and cited when re-used. Storage in King's Open Research Data System is maintained for at least 10 years. For information about what data will be shared, see section 14.2.1, under heading Data Sharing and Access. All data that will be shared openly will be anonymised.

Physical data archiving (source data on paper, Trial Master File, Site investigator files) will be done an approved secure archiving facility commissioned by King's College London. Data will be kept for seven years.

Data quality and standards

A 10% sample of data entered into the MACRO® database will be checked every three months against source data. Data management will be audited 12 monthly by the R&D Department at GSTT.

After data collection and data checking are complete and the MACRO® database has been locked, an integrated dataset will be transferred to the trial statistician.

14.1.3 Data transfer

The method of monthly transfer of anonymised baseline data from the PR-service to the trial manager, during the baseline collection period, will be agreed with the research team member at the time of the SIV. It is anticipated, from the experience gained in the feasibility study, that most services will be collecting these data on an Excel spreadsheet. Monthly transfer of data in encrypted emails with password protected attachments from the site to the research team will allow monitoring of the standard of data collection at each site and facilitate ongoing checks against the site eligibility criteria. Attendance records for PR) will be transferred by the PR-services to the trial manager on a monthly basis by encrypted email with password protected attachments for inputting into the trial database. The completed recruitment, selection and training logs will be transferred to the trial manager by encrypted email with password protected attachments. The original copies of volunteers' application forms to become PRBs and the outcomes of telephone and in person interviews will be kept in the site files. Photocopies will be taken by research staff when they visit sites and the copies will be kept in secure storage.

14.2. Access to Data for monitoring, audit, and regulatory inspections

Direct access to trial data will be granted to authorised representatives from the sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections.

14.2.1 Metadata standards and data documentation

Metadata that include descriptions of the digital data collected and saved, and methods used in the generation of data, will be retained. Analytical and procedural information documenting the provenance of the data, method of coding, and a detailed description of variable and source data will be included. These metadata will be held in the Trial Master File and kept in a secure locked filing cabinet in a locked room.

Data security and confidentiality of potentially disclosive information

Data will be only accessible remotely within the research team if strictly necessary for the operation of the trial. Individuals' data will not be used for any other purpose than that stipulated in the participant information sheet and consent form.

No patient identifiable data will be transferred from the trial database to the statistician or health economist for analysis. Data will be associated with a participant ID number only.

The main risks to data security and confidentiality of personal information will be failure to use computer and file passwords, or email encryption. The main processes for processing and storing personal and research data have been described above. The level of risk will be determined by understanding of and adherence to trial guidelines and the SOPS of the KCTU MACRO® database, GDPR regulations (https://www.ukri.org/wp-content/uploads/2020/10/UKRI-020920-GDPR-FAQs.pdf) and KCL guidelines on data management and security. The Data Controllers for this research are King's College London and Guy's and St Thomas' NHS Foundation Trust, the co-sponsors.

Risk will be mitigated by ensuring all staff undergo Good Clinical Practice (GCP) training and GDPR training every three years. A training log for each site will be kept in the site files and the PI's latest GCP certificate will be in the TMF.

Data sharing and access

Some elements of the data will be suitable for sharing. These will be rates, manner and duration of contacts between PRBs and patient-participants, details of rates of take-up and completion of PR, and the health-economic data. We will indicate in the trial website, through metadata, the types of data available and possible suitability of the data for further analysis by other users. We will follow institutional guidelines for access to the data and will be informed by MRC policy on data sharing. Processes for the sharing of data will be detailed in the formal Data Management Plan.

15. QUALITY ASSURANCE PROCEDURES

15.1. Risk assessment

The trial will be conducted in accordance with the current approved protocol, GCP, GDPR, relevant regulations and standard operating procedures. A risk assessment and monitoring plan has been prepared. It will be reviewed by the Trial Management Group at least every two months. Risk will vary over the course of the trial, reflecting significant changes in the balance of activities and short-term objectives. The risk assessment strategy is laid out in Appendix 6.

The context of the research has been complicated by the COVID-19 pandemic. Therefore, we have included new elements in the design to ensure we assess carefully possible impacts of the pandemic. The potential of COVID-19 to disrupt the return of PR services to normal working has been included as a

STOP-GO criterion at the end of the internal pilot when the Trial Steering Committee will review the establishment of the trial.

15.2. Monitoring

A training log will be maintained for the Trial Research Team to ensure that all members of the team have maintained up to date GCP and GDPR training.

The trial will have an independent TSC to which the trial will report a least once a year. The first meeting of the TSC will be before the internal pilot is started. The TSC will meet again to review the outcome of the internal pilot which will address feasibility criteria including the impact of the COVID-19 pandemic. STOP-GO criteria have been designed to address the issues of feasibility and ensure that the trial is likely to recruit and retain adequate numbers of sites, PRBs and patient participants, and that the intervention can be delivered as planned.

Personnel from the sponsor and the funder may monitor or audit the study according to the protocol, sponsor's SOPs, GCP and the application of regulatory requirements.

15.3. Trial committees

15.3.1 Trial research team

The Trial Research Team will consist of the CI, Leeds research fellow, trial manager, health psychologist, main site research assistant, Leeds research assistant and administrative assistant, where appropriate. The team will meet weekly to review the progress of the work, the achievement of targets, where appropriate and feasible. Agendas and minutes for all trial committees will be kept in the Trial Master File.

15.3.2 Trial Management Group

The Trial Management Group will consist of the co-investigators, the health psychologist, trial statistician, trial health economist, trial manager and administrative assistant, any acting members of these roles and any other appropriate members as deemed by the CI. The group will meet at least every two months at an agreed time. Its remit will be to guide the management of the trial, support the research team in achieving the trial milestones, oversee the delivery of key objectives, review the risk monitoring strategy, help in the identification and solution of management problems.

15.3.3 Trial Steering Committee

The Trial Steering Committee (TSC) will act on behalf of the Funder and the co-sponsors, where appropriate and defer decisions where relevant.

16. PROTOCOL DEVIATIONS

A trial related deviation is a departure from the ethically approved trial protocol or other trial document or process (e.g. consent process) or from Good Clinical Practice (GCP) or any applicable regulatory requirements. Any deviations from the protocol will be documented in a protocol deviation form and filed in the trial master file (TMF). A standard operating procedure should be in place describing the

procedure for identifying non-compliances, escalation to the central team and assessment of whether a non-compliance /deviation may be a potential Serious Breach.

17. SERIOUS BREACHES

A serious breach is defined as "A breach of GCP or the trial protocol which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the subjects of the trial; or

(b) the scientific value of the trial".

Breaches of the trial protocol are highly unlikely to represent a threat to the safety of participants. Serious breaches of the protocol could represent a threat to the scientific value of the trial and will therefore be reported to the sponsor within 1 working day of the breach being discovered and confirmed. The sponsor will then decide if the breach should be reported to the REC committee, HRA and the NHS host organisations within seven calendar days.

18. ETHICAL AND REGULATORY CONSIDERATIONS

18.1. Declaration of Helsinki

The trial will be conducted in accordance with the recommendations for physicians involved in research with human subjects adopted by the 18th World Medical Assembly, Helsinki 1964, as revised and recognized by governing laws and EU directives. Each participant's consent to participate in the trial should be obtained after a full explanation has been given of treatment options, including the conventional and generally accepted methods of treatment. The right of the participant to refuse to give consent to participate without giving reasons must be respected. Similarly, the participant remains free to withdraw from the trial at any point and to withdraw from follow up without giving reasons and without prejudice to their future treatment.

18.2. Guidelines for Good Clinical Practice

The CI will be responsible for ensuring this trial is conducted in accordance with the UK Governance Framework for Health and Social Care Research (2020) (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/) including Good Clinical Practice as laid out in the Framework, and its subsequent amendments and applicable legal and regulatory requirements.

A detailed review of the ethical issues arising in regard to this study has been provided in the research ethics committee application form (IRAS) and the participant study information sheets and consent forms that have been submitted with the form for review. The participant documents will cover the process of obtaining written consent, and the access, storage, and use of data collected. The study will not start until receipt of REC ethics approval, HRA approval and local NHS permissions.

18.3. Approvals

Following Sponsor approval, the protocol, informed consent form, participant information sheet and associated patient-facing documents and introductory material will be submitted to an appropriate Research Ethics Committee (REC), regulatory authorities (HRA), and host institution(s) for written approval. The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

18.4. Other Ethical Considerations

18.4.1 Consent

Consent materials comprise a Participant Information Sheet and an Informed Consent Form. We made particular effort to use clear, accessible language in these forms and have received advice on them from our study patient advisors.

All research participants will be given a copy of their signed consent form at the time of their recruitment into the study. The process of taking consent has been detailed in Section 10.3. All research team members will have received appropriate training including good clinical practice training and are experienced in the process of taking consent.

18.4.2 Participant confidentiality

Information related to participants will be kept confidential and managed in accordance with the Data Protection Act (2018) (https://www.gov.uk/data-protection), NHS Caldecott Principles (https://www.gov.uk/government/publications/the-caldicott-principles), The UK Governance Framework for Health and Social Care Research (2020) (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/), and the conditions of Research Ethics Committee Approval.

The participant information sheets will set out arrangements relating to confidentiality, security, storage of data and accessibility of data only to the study team. Participants will also be informed about transfer of any hard copy data about them to the host centre/s for secure and confidential storage. All documentation containing identifiable participant data such as in informed consent forms and contact details logs, will be stored separately from case report forms (CRFs), adverse event logs, in a locked cabinet, in a locked room. All participants will have the opportunity to contact the study research team if they require more information and the Patient Advice and Liaison Service (PALS) in each NHS Trust or local Public Health Department.

18.4.3 Conflicts of interest

There are no conflicts of interest among the research study team.

18.5. Reporting

The CI shall submit once a year throughout the clinical trial, or on request, an Annual Progress Report to the REC, HRA (where required), the sponsor and the funder, NIHR. In addition, an End of Trial notification and final report will also be submitted to the above organisations and committees.

18.6. Expenses and Benefits

PR staff, PR-buddies, and patient-participants will receive reimbursement of all out-of-pocket expenses incurred in participating in the research including travel costs, food and refreshment. Volunteer PR-buddies will receive compensation of £90 each for time taken by completion of research tasks including recording of interactions with patient-participants, and participation in research interviews and focus-groups.

19. FINANCE AND INSURANCE

19.1 Funding

The trial is solely funded by the National Institute of Health and Care Research (NIHR), award no. NIHR130999.

19.2 Insurance

The study is co-sponsored by King's College London (KCL) and Guys and St Thomas' NHS Foundation Trust (GSTT). The sponsors will, at all times, maintain adequate insurance in relation to the study. KCL through its' own professional indemnity (Clinical Trials) & no-fault compensation and the GSTT having a duty of care to patients via NHS indemnity cover, in respect of any claims arising as a result of negligence by its employees, brought by or on behalf of a study participant.

19.3 Contractual arrangements

Appropriate contractual arrangements have been put in place with collaborating institutions.

20. PUBLICATION AND DISSEMINATION

A publication policy will be written with the agreement of all co-investigators and in line with the co-Sponsors' policies on publication and dissemination. The writing of the policy will precede the planning of the first scientific paper, likely to be the trial protocol. The publication policy will cover authorship, acknowledgements, and review procedures for scientific publications. The publication policy will be consistent with any contracts or agreements made with collaborating partners.

20.1 Dissemination

The trial results will be disseminated in the following ways:

a) A dedicated website built up for the needs of the trial:
   Describing background, objectives, design, stages and timeline
   Presenting the research team, collaborating institutions, co-investigators, participating sites
   Posting updates, results, details of publications and conference presentations
   Providing restricted access to training materials
   Providing contact details
b) To participating healthcare professionals through electronic newsletters
c) To people with COPD and their carers through the British Lung Foundation
d) To healthcare providers and commissioners by direct communication with PR services and Clinical Commissioning Groups
e) Public engagement events and stakeholder meetings

f) Providing summary materials to charitable and professional associations such as the British Thoracic Society, the Royal College of General Practitioners, the Association of Chartered Physiotherapists in Respiratory Care and the Primary Care Respiratory Society, to raise the profile of the study and engage with relevant stakeholders
g) Press releases containing infographic material. Any press releases will be created in conjunction with the co-Sponsors' press offices.
h) Peer-reviewed scientific publications.

20.2 Publication

The publication aims for the trial are that at least six scientific publications will be generated:

1. Trial protocol paper
2. Main trial report
3. Acceptability of the intervention to PR sites, PRBs, and patient-participants
4. Intervention fidelity
5. Predictors of uptake and completion of PR
6. Health Economic Analysis

A publication policy will be written prior to the submission of the first publication.

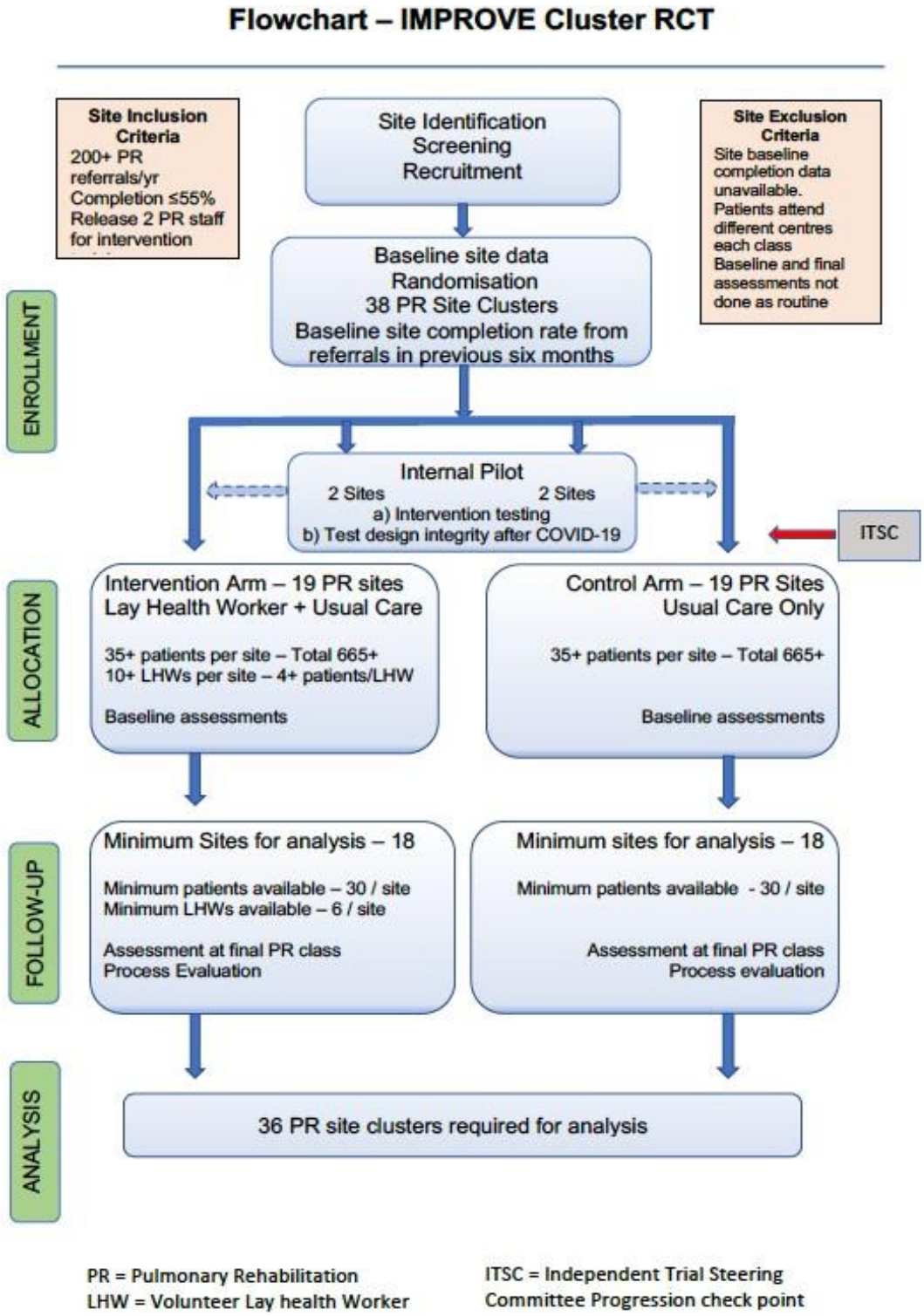
21. THE GENERATION OF INTELLECTUAL PROPERTY

21.1. Intellectual property

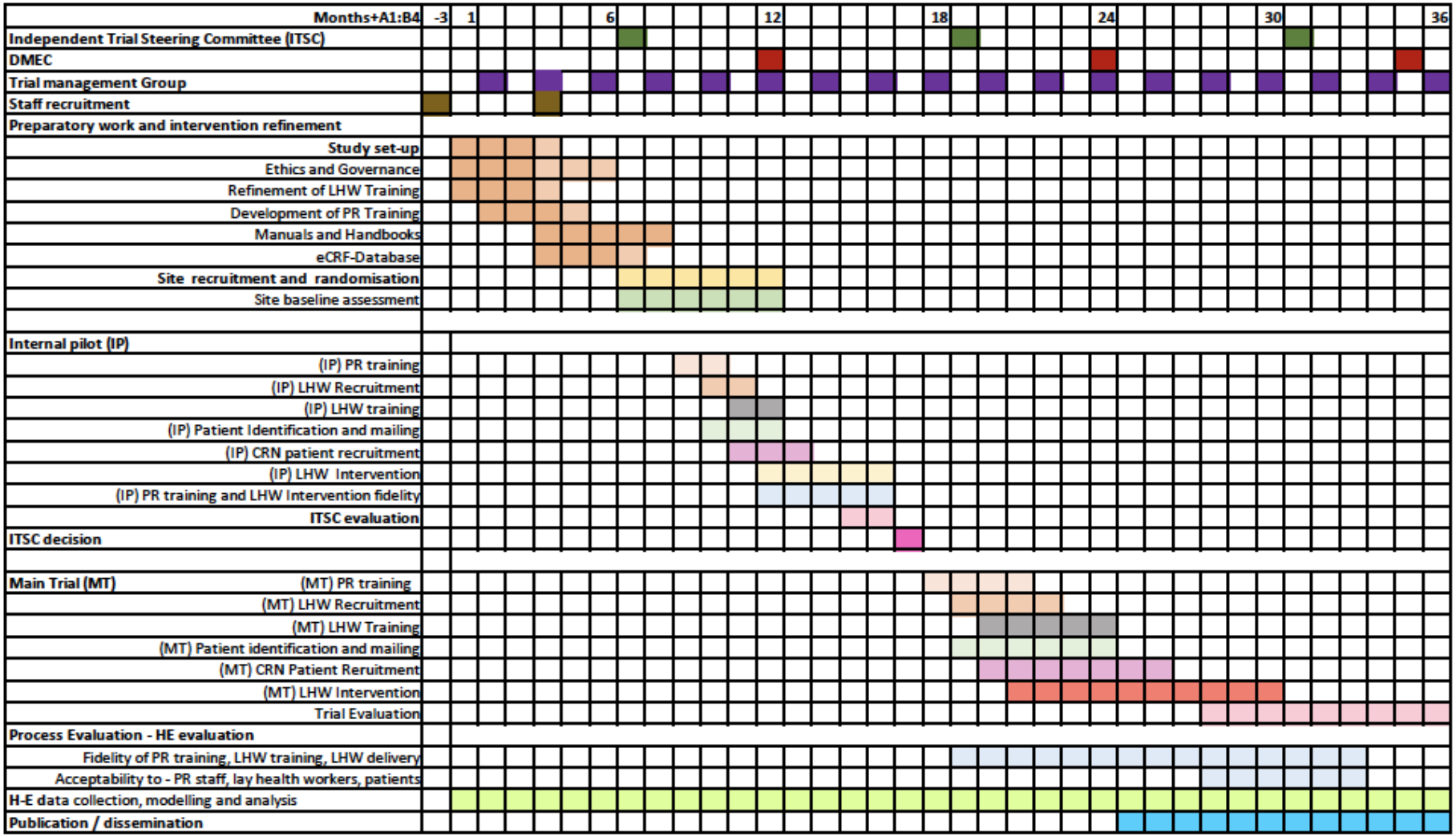
King's College London, as a co-sponsor and lead organisation, has agreed in the Collaboration Agreement between King's College London, and Guy's and St Thomas' NHS Foundation Trust, and University of Leeds and imperial College of Science, Technology and Medicine, and Queen Mary University of London, and Norwegian Institute of Public Health, with respect to new intellectual property that all information, data, know-how, results, inventions, software and other Intellectual Property arising through conduct of the Project, in accordance with the terms of the award by the funder, NIHR130999, shall be owned by the lead organisation. The lead organisation may commercially exploit the intellectual property in consultation with the other parties to the collaboration agreement. In such circumstances, the lead organisation will pay the other parties a fair and reasonable royalty rate/revenue on the value of any products or processes commercially exploited by it which incorporate any intellectual property taking into consideration the respective financial and technical contributions of the Parties to the development of the intellectual property, the expenses incurred in securing intellectual property protection thereof and the costs of its commercial exploitation and the proportionate value of the Results in any such product or process.

22. APPENDICES

22.1. APPENDIX A: TRIAL FLOW CHART



22.2. APPENDIX B TRIAL GANTT CHART



IMPROVE GANTT CHART

22.3. APPENDIX C: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
NSA 01	1.2	1/12/2022	Toby Morgan	Changes to inclusion/exclusion criteria based on discussions with sites, details of the MACRO database and randomisation added, visit windows were specified, change to CI's title

N.B. List details of all protocol amendments here whenever a new version of the protocol is produced. Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee, IRAS or HRA.

22.4. APPENDIX D: RISK ASSESSMENT AND MONITORING

Hazard	Consequences	Risk Impact Likelihood	Risk Reduction Actions	Risk Occurrence mitigation
Ethics/Governance delays	Failure to start trial on time, impact on completion	High impact High likelihood	Identify targets for submission to R&D directorate, HRA, assess time to decisions, allow for delays in timeline	
Staff				
a) Staff recruitment /retention failure/sickness	Failure to meet set-up deadlines Failure to deliver training Failure to recruit sites Failure to recruit patients Failure to conduct process evaluation	High Impact Medium likelihood	Ensure thorough recruitment processes, attention to staff welfare, and appropriate work demands. Training of PR teams and LHWs is being designed in detail with SOPs, manualised training and involvement of the Royal Society of Public Health.	.

	Failure to assess primary and secondary outcomes		Detailed training skills will be held by two members of the research team so that if one drops out through sickness or other reasons a replacement can be recruited without loss of expertise from the team. In the same way, the site recruitment, support and monitoring will be carried out by teams mirrored in London and Leeds.	
Collaborating sites [Recruitment not yet commenced]				
a) Recruitment and retention of sites	Failure to have power to make key comparison If staff leave, new staff may not wish to participate, those who do will have to be trained, and the loss of momentum with existing lay health workers could undermine site participation	High impact Medium likelihood	This is a new aspect of the intervention. We have been disseminating news of the trial. We aim to train a backup PR team member surplus to requirements in each site. We have a stakeholder group of PR team managers and staff to troubleshoot design issues before site recruitment. We have allowed for two sites withdrawing.	
b) Retention of site staff	Failure to deliver the intervention in the site	High Impact Medium likelihood	The trial has a small influence in retaining staff which is to ensure that the trial engages the whole PR team and provides adequate back-up support of the team.	
LHW participants				

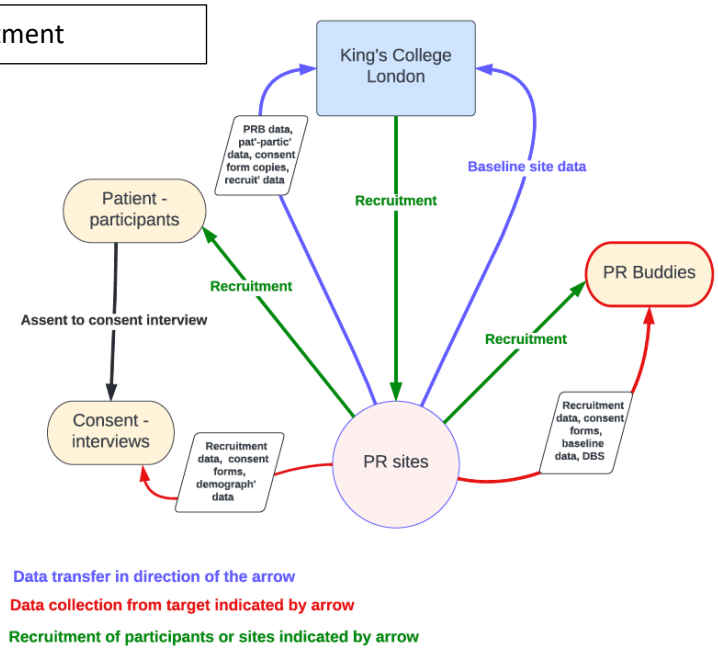
[Recruitment not yet commenced]				
a) Recruitment of LHW participants	Failure to recruit adequate LHWs per site may limit number of patients that can be supported. If severe it would undermine the trial.	High impact Low likelihood	The feasibility study gives us a detailed understanding of the issues in recruitment and retention of LHWs. We have developed LHW recruitment and training in light of that understanding	
b) Successful training in sites	The training delivery to LHWs by PR teams is one of the intervention elements.	High Impact Low Likelihood		
c) Retention of LHWs in sites	Undermining of capacity to deliver the intervention	Medium impact Low likelihood	Careful support of LHWs is the key to maximising retention. Retention was successful in the feasibility study.	
Patient participants [Recruitment not yet commenced]				
a) Recruitment of patient participants	Recruitment of patient participants and acceptance by patients of the LHW intervention are crucial to delivery of the trial. Retention in the intervention side of the trail is the primary outcome measure	High impact Medium likelihood	We have learnt a lot about recruitment of patient participants in the feasibility study, particularly the need to recruit by telephone rather than by letter. We will be able to test this in the internal pilot, learning particularly about the participation of PR teams and what additional support might be needed.	
b) Successful participation in the	Engagement with LHWs is of high importance	Medium Impact	Close involvement of the PPI group to ensure we	

intervention sites		Low Likelihood	replicate the retention of the patient participants.	
c) Retention of patient participants	Loss of consent to collect outcome data would be a significant challenge	Medium Impact Low Likelihood	This is an issue for the intervention side of the trial mainly. Ensuring LHWs treat patient participants with consideration and courtesy is important. An important element of the training.	
Data				
a) Collection of baseline data	All PR services collect data at baseline and completion. The data are not part of the primary outcome measure but important to the credibility of the trial. All PR services keep a record of patient attendances. Collection of process evaluation data is not crucial to the assessment of outcome but its explanatory role is important.	Medium impact low likelihood	PR teams have rigorous methods of data collection on patient participation. We will investigate the rigour of the participation data recording by sites prior to confirmation of recruitment as well as rates of take up and completion in the months prior to joining the trial.d	
b) Collection of primary outcome data	This would undermine the capacity of the trial to report its effectiveness		This is linked to the retention of patient participants. Prevention of hostility between LHWs and patient participants and emphasising the need for consideration and courtesy.	
Recruitment				
See sections above on sites, lay health workers and				

patient participants				
Intervention				
a) Training of PR teams delivery intervention fidelity	The first unknown in this trial is the implementation of the training of PR teams in delivering the LHW training. Failure in this component would lead to failure of the trial.	High Impact Medium Likelihood	The training of PR teams will be developed with a PPI group that contains members who have undergone LHW worker training and members who were recipients of the intervention, both in the feasibility study. A PR stakeholder group will advise on the development of the training of PR teams and the acceptability of the PR training to PR teams.	
b) Training of LHWs delivery intervention fidelity	The second unknown is the training of the LHWs by the PR teams. Failure in this component would lead to failure of the trial.	High Impact Medium likelihood	We have demonstrated the successful training of LHWs in the feasibility study. The training of LHWs is being improved. One of our team has experience in training PR teams in behaviour change techniques. This experience will be used in the training of PR teams. A PR stakeholder group will advise on the development of the training of LHWs and the acceptability to PR tea,s of the LHW training. .	

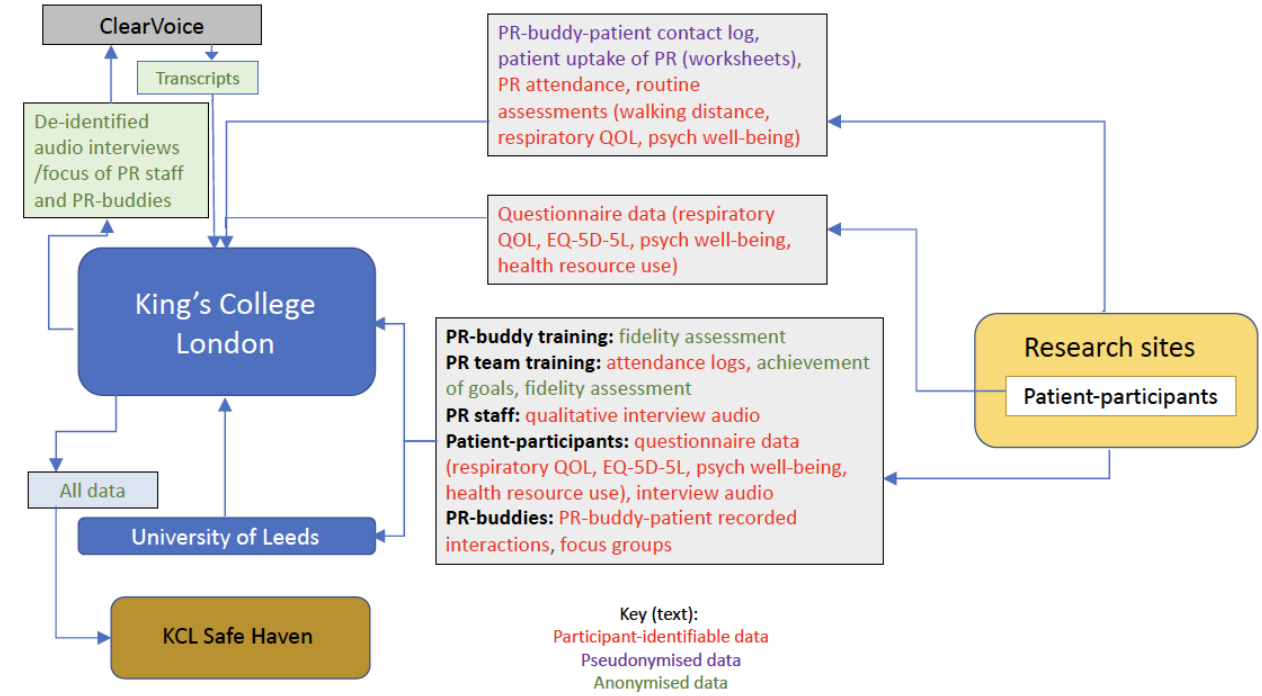
22.5. Appendix E Data flow diagrams – a) Recruitment and b) Intervention

a) Recruitment



22.6.

b) intervention



Flow of data from research sites (pulmonary rehabilitation services) to King's College London (KCL), and from research sites (pulmonary rehabilitation services) to University of Leeds and thence to KCL. De-identified audio data will be transferred from KCL to the transcription company, Clear Voice, and returned to KCL with transcribed data.

KCL Safe Haven: all trial data will be anonymised and stored in King's Open Research Data System (KORDS). Source data worksheets, completed CRFs and data stored on logs will be stored in a locked cabinet in a locked room at KCL. Physical data archiving (source data on paper, Trial Master File, Site investigator files) will use an approved secure archiving facility commissioned by KCL.

22.7. Appendix F: Overview of trial assessments and recruitment process

	Site Enrolment/ baseline	Staff Training	PR-buddy Enrolment	PR-buddy Training	Patient-participant enrolment	Follow-up		Close
TIMEPOINT						**3-months**	**6-months**	
PR SITE ENROLMENT:								
PR-staff informed consent	X							
Staff Training		X						
PR-BUDDY ENROLMENT:								
Initial phone call			X					
Eligibility screen (interview)			X					
PR-buddy training				X				
Allocation of PR-buddies to patients					X			
PR-buddy support meetings						X*	X*	
PATIENT-PARTICIPANT ENROLMENT:								
Patient-participant informed consent					X			
ASSESSMENTS:								
Rates of referrals	X							X
Rates of uptake of PR	X							X
Rates of completion for PR	X							X
Assessment of exercise capacity					X	X	X	
Outcome questionnaires					X	X	X	
Acceptability to staff patients and PR-buddies								X

Overview of the main events in recruitment and assessment of participants. Rows highlighted in yellow will take place in both arms of the trial, while rows that are not highlighted are only in the intervention arm of the trial. * indicates that this event should take place once per month.

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