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BMJ Open

Personalised Exercise-Rehabilitation FOR people with Multiple long-term conditions (PERFORM): protocol for a randomised feasibility trial

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ABSTRACT

Introduction Personalised Exercise-Rehabilitation FOR people with Multiple long-term conditions (PERFORM) is a research programme that seeks to develop and evaluate a comprehensive exercise-based rehabilitation intervention designed for people with multimorbidity, the presence of multiple long-term conditions (MLTCs). This paper describes the protocol for a randomised trial to assess the feasibility and acceptability of the PERFORM intervention, study design and processes.

Methods and analysis A multicentre, parallel two-group randomised trial with individual 2:1 allocation to the PERFORM exercise-based intervention plus usual care (intervention) or usual care alone (control). The primary outcome of this feasibility trial will be to assess whether prespecified progression criteria (recruitment, retention, intervention adherence) are met to progress to the full randomised trial. The trial will be conducted across three UK sites and 60 people with MLTCs, defined as two or more LTCs, with at least one having evidence of the beneficial effect of exercise. The PERFORM intervention comprises an 8-week (twice a week for 6 weeks and once a week for 2 weeks) supervised rehabilitation programme of personalised exercise training and self-management education delivered by trained healthcare professionals followed by two maintenance sessions. Trial participants will be recruited over a 4.5-month period, and outcomes assessed at baseline (prerandomisation) and 3 months postrandomisation and include health-related quality of life, psychological well-being, symptom burden, frailty, exercise capacity, physical activity, sleep, cognition and serious adverse events. A mixed-methods process evaluation will assess acceptability, feasibility and fidelity of intervention delivery and feasibility of trial processes. An economic evaluation will assess the feasibility of data collection and estimate the costs of the PERFORM intervention.

Ethics and dissemination The trial has been given favourable opinion by the West Midlands, Edgbaston Research Ethics Service (Ref: 23/WM/0057). Participants will be asked to give full, written consent to take part by trained researchers. Findings will be disseminated via journals, presentations and targeted communications to clinicians, commissioners, service users and patients and the public.

Trial registration number ISRCTN68786622.

Protocol version 2.0 (16 May 2023).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The trial population includes people with multiple long-term conditions, a population which often experiences a high disease and treatment burden and unmet health need.
⇒ This randomised feasibility trial will increase knowledge about the feasibility and acceptability of the Personalised Exercise-Rehabilitation FOR people with Multiple long-term conditions intervention and a full randomised controlled trial.
⇒ The primary outcome is feasibility and a range of participant outcomes will be assessed using a comprehensive range of questionnaires and endpoints.
⇒ Blinding of participants and intervention delivery staff will not be possible.
⇒ As a feasibility trial, there is no formal power calculation to determine the numbers needed to detect a statistical difference in participant outcomes at the end of follow-up.

INTRODUCTION

Multiple long-term conditions (MLTCs) (or 'multimorbidity'), defined as the presence of at least two long-term conditions (LTC) within an individual,[1] are a major global public health problem. Over one in five adults are estimated to be living with MLTCs[2 3] and this is associated with an increased risk of mortality and hospitalisation, higher healthcare costs and functional decline resulting in reduced health-related quality of life.[2–7] The 2021 Cochrane systematic review and meta-analysis of

interventions shows there to be few or no evidence-based therapies to support the management of people living with MLTCs.[8]

In contrast, a substantial body of evidence has demonstrated improvements in functional capacity, health-related quality of life and reduced risk of hospital admissions following structured exercise-based rehabilitation for several different single LTCs.[9–15] However, the current models of delivery of exercise-based rehabilitation across many international healthcare systems have important limitations for adults with MLTCs.[16–18] First, current provision is dominated by rehabilitation services targeted at cardiovascular or pulmonary conditions. Second, these rehabilitation programmes are effectively single disease in their focus, and therefore, not formally designed to consider the more complex and wider health needs of people living with MLTCs. Consequently, while these rehabilitation health professionals may be specialists in cardiopulmonary disease, they are not necessarily all trained to manage the broader rehabilitation needs for other LTCs. As a result, the potential benefits of exercise-based rehabilitation are not currently available to many people with MLTCs.

The Personalised Exercise-Rehabilitation FOR people with Multiple long-term conditions (PERFORM) is a research collaboration and programme funded by the National Institute of Health Research that seeks to develop and evaluate a comprehensive exercise-based rehabilitation intervention specifically designed for people with MLTCs.[19] This paper describes the protocol for a trial to assess the feasibility and acceptability of the PERFORM intervention, study design and processes.

AIMS AND OBJECTIVES

Aim

To implement the PERFORM intervention across three sites and assess the feasibility and acceptability of the PERFORM intervention and trial methods to inform the design of a full randomised controlled trial to assess clinical and cost-effectiveness.

Objectives

1. To assess participant recruitment and retention.
2. To assess the feasibility, acceptability of the intervention exploring barriers and facilitators to uptake and engagement from both participant and healthcare provider perspectives.
3. To assess the fidelity and reach of the PERFORM intervention.
4. To further refine the PERFORM intervention and programme theory.
5. To assess the feasibility and acceptability of data collection tools.
6. To obtain estimates of key cost drivers.

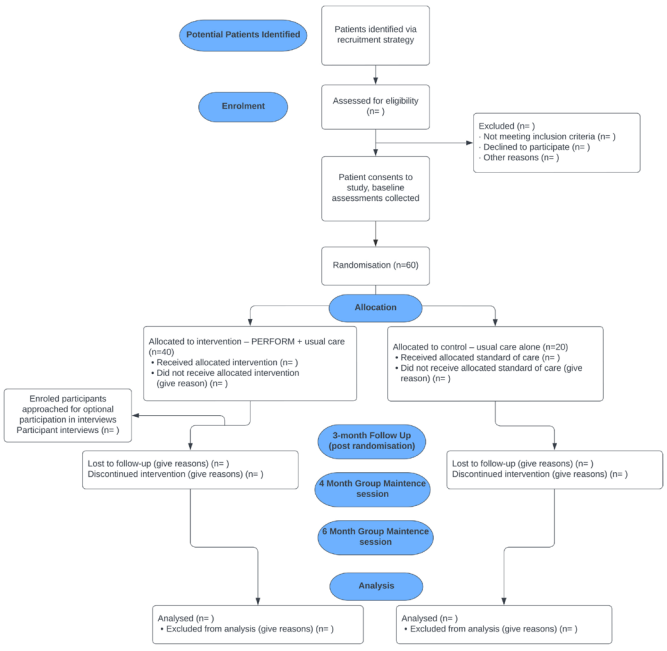

Figure 1 PERFORM feasibility study flow chart. Flow chart demonstrates the participant journey within the study from identification through to analysis, where applicable. PERFORM, Personalised Exercise-Rehabilitation FOR people with Multiple long-term conditions.

7. To assess risks of bias/contamination.
8. To assess whether progression criteria are achieved.

METHODS AND ANALYSIS

This protocol is reported in accordance with the Standard Protocol Item Recommendations for Interventional Trials 2013 guidance.[20]

Study design

The trial is a parallel two-group randomised feasibility study with nested process and economic evaluation. Patients will be randomly allocated in a 2:1 ratio to either the PERFORM intervention plus usual care (intervention) or usual care alone (control). The trial seeks to recruit of total of 60 participants recruited over a 4.5-month period; 40 participants allocated to the intervention group and 20 participants to the control group. Inclusion and follow-up of participants are summarised in figure 1.

Trial setting

The trial will be conducted in three UK sites that have established expertise/capacity in the delivery of exercise rehabilitation interventions to people with cardiac or pulmonary disease. Sites will be located within either an acute hospital or a community service.

Trial participants

Participants with MLTCs will be recruited from several sources, including from relevant medical specialties and primary and secondary care. Inclusion criteria for the study are:

- Adults ≥18 years old.

- Participants need one with at least one LTC with evidence of the beneficial benefits of exercise,[21] that is, one from the following listing: arthritis, asthma, atrial fibrillation, bronchiectasis, cancer, chronic kidney disease, chronic obstructive pulmonary disease, connective tissue disease (pain), coronary heart disease, dementia, depression, diabetes mellitus, heart failure, hypertension, long-covid, multiple sclerosis, osteoporosis, painful condition, Parkinson's disease, peripheral vascular disease, polycystic ovarian syndrome, psychoactive substance misuse, stroke or transient ischaemic attack plus at least one other LTCs from a list of 45 LTCs based on Cambridge Multimorbidity Score.[22]
- To be mobile (including the use of walking aids).
- Able and willing to provide informed consent.

Exclusion criteria for the study are:

- Unable to give consent for the study.
- Unable to communicate in English (carer or support worker may be available).
- Known contraindications to exercise (as defined by the American College of Sports Medicine (ACSM).[23]
- Unsafe to exercise in a group without 1:1 supervision (eg, significant risk of falls).
- Unable to attend in-person training sessions.
- Participation in an exercise rehabilitation programme in the last 6 months.
- Unstable psychiatric disorder that limits or disrupts group-based interventions.
- On an end-of-life pathway with an expected prognosis of <12 months.
- Active malignancy (on chemotherapy/radiotherapy/planned urgent surgery).
- For people on a surgical waiting list a pragmatic decision will be made on a case-by-case basis of the type of surgery, urgency and likely wait times.
- Pregnancy.
- Living in a nursing home.

Consent

Trial researchers trained in Good Clinical Practice will obtain consent from participants to take part in the trial (online supplemental appendix A). Participants can withdraw at any time from the study without giving reasons and without prejudicing his/her further treatment.

Randomisation

Randomisation and allocation will be coordinated by Leicester Clinical Trials Unit (LCTU), a UKCRC registered Unit and independent of the research team at sites. LCTU will supply a web-based randomisation system from a third party (Sealed Envelope). Randomisation will use random permuted blocks within strata of site. To maintain concealment and minimise selection bias, randomisation will be performed after the baseline visit using a secure validated password-protected web-based system supported by LCTU.

Intervention

The PERFORM rehabilitation programme was co-designed with patients, service providers and service commissioners, following the principles of intervention mapping and using other recognised intervention development techniques including: (1) stakeholder involvement workshops to identify key barriers and enablers and key target self-care behaviours; (2) synthesis of existing evidence to identify the target population (as above) and (3) iterative identification of intervention strategies and behaviour change techniques designed to address the identified barriers and reinforce enabling factors and maximise patient engagement.[24]

The intervention comprises an 8 week supervised group-based rehabilitation programme that will be offered in either a primary or secondary care setting. Sessions will be delivered twice a week for the first 6 weeks and once a week for the last 2 weeks (n=14). Each session will last for 2 hours (1 hour of supervised exercise and 1 hour of self-care support including discussion and self-care planning around a range of common issues for people with MLTCs). The intervention will be offered within 4 weeks of the initial assessment. Participants will also be offered group-based maintenance sessions at 4 months postrandomisation and 6 months postrandomisation (n=2). These sessions will provide an opportunity to review long-term progress, provide additional support to participants and address any further questions they may have after the 8-week supervised intervention period.

Exercise training sessions will be individually prescribed and progressive, focusing on both increasing aerobic fitness and improving physical functioning. Training intensity will be set at >70% of maximum, based on performance of the incremental shuttle walking test (ISWT) as a measure of maximal capacity.[25] The programme will aim for bouts of 30 min of exercise, 5 days per week. Resistance training of the major muscle groups will be delivered based on ACSM guidance for older adults (3 sets of 10–12 exercises performed on at least 2 non-consecutive days per week).[23 26] Participants will also be asked to supplement supervised sessions with an individually tailored home exercise programme, which will be closely monitored, with the exercise prescription progressed as appropriate. The home exercise programme and self-care activities will be captured in a standardised 'Progress Tracker' diary that requires the participants to record exercise frequency, duration and effort scores, their overall goals for change and specify changes in self-care behaviours and identify any changes in self-care that impact on their physical and mental well-being.

'Health and Well-being' self-care support sessions aim to support self-management of common symptoms and risk factors and to enhance self-management skills, including problem-solving, planning, self-monitoring and cognitive adaptation. The list of core sessions that will be delivered to participants randomised to the intervention arm (in no particular order) are detailed:

- Exercise is medicine (learning about exercise and its role in staying healthy).
- Eating for health: staying strong.
- Better sleep.
- Lifting your spirits (improving mood/tackling depression).
- Eating for health: a healthy balanced diet.
- Managing pain (strategies for reducing pain).
- Staying active for life (planning for an active future, beyond the PERFORM programme).
- Stress busting (recognising and addressing stress and anxiety).
- Breathe easy (reducing breathlessness).
- Stronger together (increasing/improving support networks).
- Boost your energy (improving energy levels/reducing fatigue).
- Making the most of your medications (including ways to identify and manage side effects).
- Let's relax (practising relaxation techniques).
- Coping well (strategies for living well despite having MLTCs).

Much of the advice will be appropriate to all participants irrespective of their specific LTCs, for example, healthy eating, benefits of exercise, stress management and relaxation techniques, and medication adherence. Caregivers (family or friends that the patient wishes to invite) will be welcome to attend the Health and Well-being sessions. Information will be supplemented by written leaflets and other materials to support the individual to share with their family and carers.

The PERFORM programme will be delivered by trained healthcare professionals (eg, physiotherapist, nurse, exercise specialist) according to current pulmonary and cardiac rehabilitation standards[27 28] with a minimum ratio of one staff member per eight patients and a minimum of two healthcare professionals in any session.

Control

Both intervention and control groups will receive usual care, that is, continue to manage their MLTCs as advised by their primary/secondary care team. This includes continuation with medication, other treatments and medical follow-up visits. After the initial assessment, those allocated to the control group will continue with their usual care alone.

Outcome measures and progression criteria

Outcome data will be collected at baseline (prerandomisation) and 3 months postrandomisation (see figure 2). The 3-month time point coincides with the end of the 8-week intervention delivery period for participants in the intervention arm and allows a 1-month period after the baseline visit for completion of randomisation and referral processes. The baseline assessment will be completed by a member of the research team and includes participant outcomes listed below plus participant demographics and medical history (age, gender, ethnicity, marital/civil partnership status, living situation, smoking status, employment status, education status, postcode, caring responsibility, medical history (including LTCs, height, weight, resting blood pressure/heart rate and respiratory

Procedures	Feasibility Study Visits							
	Pre Screening	Screening and Baseline	Intervention Phase (within 4 weeks of randomisation)	Discharge appointment (1 -2 weeks after completion of Intervention)	3-Month Follow-Up (3 months post-randomisation ± 4 weeks)	Optional Interviews (after completion of Intervention Phase for participants)	4 month group maintenance Session (Intervention patients only 4 month post randomisation)	6 month group maintenance Session (Intervention patients only 6 month post randomisation)
Invitation	X							
Eligibility assessment		X						
Informed consent		X						
Randomisation		X						
Baseline assessments		X						
Intervention or control			X					
Intervention discharge assessment				X				
Outcome questionnaires		X			X			
Follow-up assessments					X			
Resource use data collection questionnaire					X			
Patient & provider interviews						X		
Maintenance session							X	X

Figure 2 Summary of PERFORM feasibility data collection. Figure indicates all the assessments within the feasibility study and their allocated time points for completion. PERFORM, Personalised Exercise-Rehabilitation FOR people with Multiple long-term conditions.

Table 1 PERFORM feasibility study progression criteria criteria to be used by the programme steering committee (PSC) in assessing progression to WP4

	Red	Amber	Green
Recruitment % of target of 60 participants met in 4.5 months following site opening	<75%	75%–99%	100%
Retention % of patients with complete EQ-5D data at 3-month follow-up)	<65%	65%–79%	80%–100%
Intervention adherence/attendance	<40% of patients attend ≥60% of sessions	<50% of patients attend ≥60% of sessions	60%–100% of patients attend ≥60% of sessions

Red: do not progress to the main trial, Amber: progress if action plan to mitigate problems can be determined and agreed with the PSC, Green: progress directly to the main trial.
EQ-5D, EuroQoL-5 Dimensions; PERFORM, Personalised Exercise-Rehabilitation FOR people with Multiple long-term condition.

frequency) and concomitant medicines. A blinded assessor, with no knowledge of treatment allocation, will collect outcomes at follow-up. Efforts to maximise participant retention include a trial newsletter sent to sites and payment to participants for data collection visits. We will attempt to collect follow-up data from all participants regardless of whether they discontinue or deviate from the intervention.

Primary feasibility outcomes

The primary outcome of this feasibility trial will be to assess whether prespecified progression criteria are met to progress to the full randomised trial to assess the clinical and cost-effectiveness of the PERFORM intervention. Progression criteria are based on trial recruitment, retention and intervention adherence (see table 1). Progression criteria were agreed with the project funder and the programme steering committee (PSC).

The following will be coprimary outcomes as they all form part of the progression criteria:

- Recruitment: calculated as percentage recruitment target (60 participants) met at end of 4.5 months recruitment period.
- Retention: calculated as the percentage of patients randomised with complete EuroQoL-5 Dimensions (EQ-5D) data (our current proposed primary outcome for the full randomised trial) at 3 months follow-up.
- Intervention adherence: proportion of participants allocated to PERFORM intervention achieving ≥60% of sessions attended at end of supervised intervention (ie, ≥9 out of the 14 core sessions). Adherence will be measured for each individual participant, which will be collected using attendance registers taken at each exercise session.

Other feasibility outcomes

Risks of bias/contamination: Outcome assessor blind breaks will be recorded and control participants asked if they have received PERFORM intervention at their 3 month follow-up visit.

Estimates of key cost drivers: See economic evaluation section (see below).

Further refinement of the intervention and programme theory: This will be undertaken at the end of the feasibility trial and primarily be informed by data from the process evaluation (see below).

Feasibility and acceptability of data collection tools: In addition to the co-primary of retention, we will assess the proportion of randomised participants with complete outcome data at 3-month follow-up. Participant outcome completion burden will be assessed as part of the process evaluation (see below).

Feasibility and acceptability of intervention: In addition to the coprimary of adherence, this will be assessed through qualitative interviews with patients and PERFORM intervention providers (see process evaluation section).

Participant outcomes

The following participant outcomes will be collected at baseline and 3-month follow-up:

Physical assessment tests

- Exercise/functional capacity: ISWT.[29]
- 4 m gait speed.[30]
- Hand grip strength.[31]

Participant-reported outcomes

- Health-related quality of life: EQ-5D-5L.[32]
- Mood: Patient Health Questionnaire-9[33] and Generalised Anxiety Disorder Assessment-7.[32 34]
- Physical activity: International Physical Activity Questionnaire.[35]
- Frailty: Frieds criteria.[34 36]
- Fatigue: Functional Assessment of Chronic Illness Therapy-Fatigue.[37]
- Pain: Brief Pain Inventory.[36 38]

- Health and disability: WHO Disability Assessment.[39]
- Breathlessness: Dyspnoea-12 questionnaire.[40]
- Sleep: Medical Outcome Study Sleep Scale.[41]
- Cognition: Montreal Cognitive Assessment.[42]
- Multimorbidity Treatment Burden Questionnaire.[43]
- ICEpop CAPability Measures for Adults.[44]
- Exercise adherence: Exercise Adherence Rating Scale.[45]

Clinical events

- Mortality, hospital admissions and primary care contacts.

Social and healthcare utilisation

- Assessment of social and healthcare utilisation including medication.[46]

Safety

- Serious adverse events (SAEs): Any adverse event or adverse reaction will be regarded as serious if it results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity. All SAEs that occur during the trial will be recorded and reported to the sponsor and the PSC (see below).

Sample size

To achieve the objectives of this feasibility trial, a total of 60 patients will be recruited over 4.5 months.[47] As we are interested in the acceptability of the intervention, we aim to randomise 40 participants to the intervention group and 20 to the control group. We anticipate a loss to follow-up of up to 20% at 3 months.

Process evaluation

The process evaluation will explore the feasibility and acceptability of both the intervention and the study design, and it will be conducted following the Medical Research Council guidelines for process evaluation of complex interventions.[48] A key aim of the process evaluation will be to assess and refine the programme theory in preparation for a full trial. In addition, it will assess: (1) intervention elements, that is, acceptability, context, fidelity, exposure, reach and (2) study-related elements, that is, acceptability of trial methods including recruitment, outcome measures and contamination.

Quantitative process data will include attendance at sessions and fidelity assessments. The fidelity assessment will be completed using randomly selected audiorecorded and videorecorded sessions and a fidelity checklist developed by the trial team, building on methods used in our prior intervention studies.[49] We will assess up to 24 individual initial assessments and 24 follow-up phone calls (~8 per site). We will assess (by direct observation/researcher site visit) 9–12 of the group exercise sessions (3–4 visits per site), these will include a mixture of early, mid and late sessions per group. Finally, we will audiorecord all the postexercise self-care support sessions and assess a sample of 24–30 of these (8–10 per site), reflecting the full range of session topics. Two team members will rate these sessions and inter-rater reliability will be assessed using a simple percentage agreement score for each checklist item. We will also: (1) ask staff delivering the PERFORM intervention to report confirmation that intended content (ie, exercises, self-care topics, facilitation techniques) were taught, (2) ask therapists to report both clinic observations of adherence to exercise and their assessment of home exercises performed by patients unsupervised and (3) patient reports of exercise adherence (based on intervention participants completing a weekly Progress Tracker diary during the supervised first 8 weeks).[50]

Qualitative process data will include semistructured telephone interviews with intervention participants (~30) and delivery staff (~12). Participants will be purposively sampled to include a range of conditions, gender, age, socioeconomic status and engagement with the intervention. We will also aim to interview those who did not attend the PERFORM intervention or those who were low attenders to inform improvements to the intervention. We will recruit from trial participants who will be asked to consent to be contacted about the interviews as part of the baseline assessment. They will then be contacted to see if they are willing to take part in the interviews, and if so, informed consent will be obtained (online supplemental appendix B). Two intervention staff and 2 referrers per site (12 in total) will be interviewed to inform recruitment for the main trial and identify any implementation issues.

Interviews will take place after the 8 weeks PERFORM intervention supervised period is completed and will explore the acceptability of the recruitment process and outcome measures; acceptability of the intervention; impact of the intervention on behaviour; barriers and facilitators to engagement, staff training, suggestions for improvements as well as contextual factors influencing intervention impact. Interview schedules will be guided by the PERFORM programme theory and normalisation process theory (NPT),[51] an implementation theory that has been used extensively to explore the processes underpinning implementation, embedding and integration of service innovations. We will explore potential mechanisms of intervention effectiveness and of engagement with the intervention. Interviews will be audiorecorded and transcribed verbatim.

Economic evaluation

The economic evaluation will determine the feasibility of identifying, measuring and valuing the relevant resource use, health-related quality of life and capability well-being data required to conduct the full cost-effectiveness/cost–consequences analysis in a proposed full randomised trial.[46 52] Key cost drivers will be identified within this feasibility trial using data gathered from a specially designed resource use questionnaire as well as from an intervention costing exercise (identifying and measuring all aspects of resources used to deliver the intervention).

All healthcare, personal social service resource, employment data and personal costs will be documented at the 4-month follow-up by completion of healthcare resource use questionnaires and collection of concomitant medication usage as reported by participants. The questionnaire will be tailored to the resource use requirements of people with MLTCs (and informed by resource use analysis conducted in work package 1 of the PERFORM research programme[19]). Incorporation of the full spectrum of outcomes beyond the quality-adjusted life-year/EQ-5D within a feasibility cost–consequences analysis framework will further provide initial insights to this pragmatic economic evaluation for a population with MLTCs. This feasibility economic evaluation component will also provide an opportunity to inform broader workforce impacts and other service configuration resources required to deliver the PERFORM intervention (eg, facilities, equipment) identified during the intervention development stage.

Data analysis and presentation

The number recruited and the percentage of the recruitment target and recruitment rate per site will be reported. The number and percentage (and 95% CI) retained at 3 months, defined as having complete EQ-5D data (proposed primary outcome for full trial) at 3 months follow-up, will be calculated for all patients randomised (intention to treat population). The number and percentage (and 95% CI) of patients randomised to the PERFORM intervention that attended ≥60% of sessions will be reported. In addition, the percentage of sessions attended by individuals in the PERFORM intervention arm will be summarised using median and IQR.

The number and proportion of patients randomised with complete data for each of the outcomes measured at follow-up will be calculated in all randomised patients and by randomised group. Patient-reported outcomes at 3 months follow-up and the number of each of the clinical events within 3 months follow-up will be summarised by randomised group and overall using mean (SD) and median (IQR) for continuous variables and count (percentage) for categorical variables. Intervention-control between group mean differences and 95% CIs will be reported. The number of SAEs will be presented overall and by randomised group. The number of patients with 0, 1, 2 etc events will be summarised overall and by randomised group. Given the feasibility nature of the trial, no p values will be reported.

Qualitative data will be analysed using thematic analysis.[53] Themes identified from intervention staff and patient data regarding intervention delivery will be conceptualised through an NPT lens[51] and a theoretical lens based on the programme theory/logic model. Recommendations for refining/improving the intervention will be summarised and used to refine the intervention materials and the facilitator-training course as well as updating the programme theory.

A detailed statistical analysis plan, process evaluation framework, qualitative analysis plan and health economics analysis plan, will be prepared to guide data collection and analyses. These plans will be finalised prior to final data lock and agreed with the PSC.

Patient and public involvement

The PERFORM Patient Advisory Group (PAG) has been established help to inform the PERFORM research programme.[19] The PAG is coordinated by a dedicated academic PPI lead (TI) and includes nine lay members with lived MLTCs. The PAG has contributed to the design of the feasibility trial (including patient-facing documentation) and will be involved in the ongoing management of the study and dissemination of findings.

Data management

LCTU will be responsible for data management for the trial and will undertake data validation, database queries/reviews in line with their Standard Operating Procedures. A summary of trial data collection is shown in figure 2. Source data are defined as the first-place data are recorded and will include medical records, paper case report forms (CRFs) and participant-reported outcome questionnaires. Records of trial participant data will be made on trial-specific electronic CRFs. Trained member(s) of the site research team will enter data directly into a commercially available web-based MACRO Clinical Data Management System (CDMS). On-entry validation checks will be applied where required and data entered will be checked for completeness, accuracy and timeliness by the site research team/trial manager/trial coordinator/data manager, with queries managed using the data clarification functionality within the CDMS system. A summary of trial data flow is provided in online supplemental appendix C. The trial researchers will seek consent from participants to recontact them about taking part in future ethically approved research. A data management plan will be created with specific details on data handling and record keeping. The coinvestigators and trial team will have access to the final trial pseudonymised dataset; participants are given the option at consent for their pseudonymised information to be stored indefinitely in a specialist data centre/repository for future UK ethically approved research, however, this is completely optional and does not affect their participation in the trial.

Trial management

Programme management group (PMG) comprising the chief investigators (SJS and RT), coapplicants (SAS, RAE, SB, EM, SGD, PJD, NG, CG, BJ, KJ, FM, PO and SS), members of LCTU (HRG and AB) and a PAG representative (TI) will meet quarterly and review the progress of PERFORM research programme. The PMG will report to the PSC. Monthly operational meetings of feasibility trial leads (SJS and REA) and LCTU will provide continuous monitoring of feasibility trial progress.

A PSC has been established to provide independent expert oversight of the PERFORM research programme and includes trial steering committee and data safety and monitoring committee responsibilities for the feasibility study. PSC meetings will normally take place once a year to provide overall supervision of the trial and ensure that the trial is conducted to the rigorous standards set out in the guidelines for good clinical practice. The PSC consists of an independent chair, an independent statistician, other independent members who are experts in rehabilitation and multimorbidity. The PSC will consider progression to full randomised trial following completion of the feasibility trial and will report to the sponsor and the funder. Routine reports reviewed by the PSC will include a summary of all SAEs.

Trial status

Three sites have agreed to participate (University Hospitals of Leicester NHS Trust, Newcastle upon Tyne Hospitals NHS Foundation Trust and Reach for Health Centre, Daventry, Northamptonshire). The first site began participant recruitment on 6 September 2023. At the time of this manuscript (15 November 2023), 19 participants have been randomised. We anticipate completion of the feasibility trial by May 2024.

ETHICS AND DISSEMINATION

Research ethics approval

The trial is approved by the West Midlands, Edgbaston Research Ethics Service (Ref: 23/WM/0057). The trial protocol has been agreed and accepted and the chief investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, Good Clinical Practice guidelines, the sponsor's (and any other relevant) SOPs and other regulatory requirements. The trial is sponsored by the University of Leicester Research Governance Office (reference number 0888; rgo@leicester.ac.uk, https://le.ac.uk/research/regi). The sponsor reviewed and approved the study protocol and documents suggesting some small amendments. The sponsor will not have input into data collection, management, analyses or interpretation of data or publication. There are no plans to offer post-trial care for participants other than usual care, with any compensation for harm for trial participants covered by the sponsor's insurance. Written informed consent will be obtained from all participants prior to study enrolment (online supplemental appendix A).

Dissemination

Findings will be published in peer-reviewed journals and presented at local, national, and international meetings and conferences to publicise and explain the research to clinicians, commissioners and service users. Request for anonymised feasibility trial data (quantitative and qualitative data) can be made by request to the PERFORM research team.

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Contributors SJS and RT are co-chief investigators and will oversee the design and implementation of the trial. SAS and RAE are the feasibility trial work package leads. SAS leads the embedded process evaluation with input from CG and PJD. AB and HRG assisted by ZA, are responsible for managing the delivery of the trial. SB is responsible for the statistical aspects of the trial. EM leads the health economics evaluation. CG and PJD designed the intervention and NG is responsible for the implementation of the intervention. SGD, PD, TI, BJ, KJ, FM, PO and SS are coinvestigators who were all involved in the design of the trial and attend regular programme meetings where advice is provided where needed. All coinvestigators and researchers contributed to the development of the protocol. HRG and SAS drafted the manuscript which is written on behalf of the PERFORM Programme Management Group. All authors read and approved the final manuscript.

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Competing interests SAS is President of the UK Society of Behavioural Medicine. She has also been a member of the NIHR HTA Clinical Evaluations and Trials Committee (2016–2020), the Commissioning Panel for the NIHR Policy Research Programme (2019–2022); the Chief Scientist Office Health Improvement Protection and Services committee (2018–2023). RAE is ERS Group 01.02 Pulmonary Rehabilitation and Chronic Care Secretary and ATS Pulmonary Rehabilitation

Assembly Chair. KJ is subcommittee chair for the NIHR Programme Grants for Applied Health Research, however, the honorarium for this role goes to KJ's institution, the University of Birmingham. FM is co-lead for the international working group on Minimally Disruptive Medicine, which aims to improve care for people with multimorbidity. SMS is a board member of the ExWell medical in Ireland, which is a not-for-profit organisation that provides group based medical exercise classes in community settings for people living with chronic conditions. SJS has also conducted presentations for the Ministry of Justice, is on the NICE Expert Adviser Panel for Long COVID, and was previously on the Wales Long COVID Advisory Board and the NHS-E Long Covid Your Covid Recovery working group. SJS was previously Pulmonary Rehabilitation Assembly Chair, Clinical Lead for RCP Pulmonary Rehabilitation Accreditation Scheme and Clinical Lead for NACAP Audit for Pulmonary Rehabilitation. All coinvestigators on the grant funding this work are partially supported by the National Institute for Health and Social Care Research (grant number NIHR202020).

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