

# Personalised exercise rehabilitation for people with multiple long-term conditions: a feasibility study

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<b>Registration date</b> 24/05/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/09/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

There is an increase in the number of people who have multi-morbidity – in other words, two or more long-term conditions – such as high blood pressure, diabetes, chronic obstructive pulmonary disease (COPD), osteoporosis, asthma and Parkinson’s disease (this is not an exhaustive list)/ This is due to a generally increasing life expectancy in the population. Such people can experience a reduced quality of life and have an increased risk of hospitalisation and premature death.

Previous research has shown that undertaking a supervised 8-12-week programme of exercise-based rehabilitation can improve quality of life and well-being and reduce the risk of hospital admissions of people with single long-term conditions. However, we don’t have a good understanding of the effects of exercise-based rehabilitation in people with multiple long-term conditions. Access to exercise-based rehabilitation was also identified as a priority by patient and public involvement (PPI) representatives.

In this study the researchers will develop a personalised exercise-based rehabilitation programme called PERFORM to specifically meet the needs of people with multiple long-term conditions, as well as a structured programme of supervised exercise training. The aim is to find out whether a personalised exercise-rehabilitation programme provides different results than the standard of care patients would receive through the NHS.

### Who can participate?

Patients aged 18 years and over who have two or more long-term conditions that are identified as having a potential benefit to an exercise rehabilitation programme

### What does the study involve?

All participants will be asked to attend an initial (baseline) research visit and a final (follow-up) research visit 3 months later. These visits will take place at their local hospital or rehabilitation clinic and take about 3 hours to complete. They will include walking tests and hand grip strength tests and if randomly allocated to receive the exercise rehabilitation, patients will receive a personalised exercise programme with health and wellbeing education sessions. Participants who receive the exercise rehabilitation programme will also have the opportunity to take part in

an interview that includes their thoughts on the programme, the barriers or facilitators whilst taking part and suggestions for improvement.

What are the possible benefits and risks of participating?

The PERFORM rehabilitation programme is aimed to help people manage their multiple long-term health conditions and participants may experience some benefit in taking part, but this intervention is being tested therefore benefits are not guaranteed. The information collected may help in caring for other patients in the future

There are minor disadvantages of taking part; these include travel to and from the research centre and the time taken to complete the above-listed assessments.

The researchers don't expect patients to be harmed in any way by taking part in our study, but they could experience some discomfort when completing the walking assessments. Also, if the participant is chosen to take part in the PERFORM rehabilitation programme this will involve exercise and there is a risk that they might initially have muscle soreness.

Where is the study run from?

University of Leicester (UK)

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

January 2023 to May 2024

Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?

Prof. Sally Singh or Prof. Rod Taylor

PERFORMLCTU@leicester.ac.uk

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Sally Singh

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### Type(s)

Public

**Contact name**

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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

321067

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

IRAS 321067, CPMS 55575

**Study information****Scientific Title**

Personalised Exercise-Rehabilitation FOR people with Multiple long-term conditions (multi-morbidity) (PERFORM): a feasibility study

**Acronym**

PERFORM Feasibility

**Study objectives**

Patients with two or more long-term conditions who are randomised into the PERFORM Rehabilitation Programme will have a greater improvement in their overall health, compared to patients randomised into the standard-of-care control group.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 09/05/2023, West Midlands Edgbaston Research Ethics Committee (3rd Floor, Barlow House, Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8070, +44 (0)207 104 8019, +44 (0)2071048089; edgbaston.rec@hra.nhs.uk), ref: 23/WM/0057

**Study design**

Multi-centre interventional randomized feasibility study

## Primary study design

Interventional

## Study type(s)

Other, Quality of life

## Health condition(s) or problem(s) studied

Long-term conditions

## Interventions

Current interventions as of 24/07/2023:

A parallel two-group randomised feasibility study with a nested process and economic evaluation. Patients will be randomly allocated to either intervention (PERFORM rehabilitation programme + usual care) or control (usual care alone). Randomisation is completed via an electronic system called Sealed Envelope in a ratio of 2:1. The feasibility study will be conducted across three sites with a total of 60 participants recruited over a 4.5-month period, with 40 participants randomised to the intervention group and 20 participants to the control group with a 3-month follow-up after randomisation and 2 maintenance sessions at 4 and 6 months.

The intervention is a personalised exercise rehabilitation programme for patients with two or more long-term conditions. Healthcare professionals, like physiotherapists, will be trained by the PERFORM team and all training materials are provided. The rehabilitation programme will be delivered face-to-face in a group session. The intervention may be delivered in a research or hospital rehab clinic/facility or from a gym or sports centre, depending on the site.

Participants who are randomised to receive exercise will receive 8, 6 weeks twice weekly and 2 weeks, once a week, the intervention is for 2 hours of personalised exercise rehabilitation. All participants will complete a 3-month post-randomisation follow-up visit and will repeat the assessments.

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Participants who are randomised to receive exercise will receive 6 weeks twice weekly intervention for 2 hours of personalised exercise rehabilitation. All participants will complete a 3-month post-randomisation follow-up visit and will repeat the assessments.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Assessing whether pre-specified progression criteria are met to progress to the full randomised trial, and assessing the clinical and cost-effectiveness of the PERFORM intervention by analysing the:

1. Proportion of recruitment target recruited, calculated as percentage recruitment target (60 participants) at the end of 4.5 months recruitment period
2. Retention at 3 months, calculated as the percentage of patients randomised with complete EQ-5D data at 3 months follow up
3. For patients randomised to the PERFORM intervention: proportion of patients achieving  $\geq 60\%$  of sessions attended at end of intervention (proportion of sessions attended will be calculated from the number of sessions attended out of the scheduled 12 sessions)

## **Key secondary outcome(s)**

1. The feasibility and acceptability of data collection tools assessed by measuring the proportion of patients with complete outcome data and quality of life data at 3-month follow up and using process evaluation patient interviews at 3 months
2. Key cost drivers estimated by economic evaluation 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) at 3 months. All healthcare, personal social service (PSS) resources, employment data, and personal costs will be measured within this feasibility study.
3. Risks of bias/contamination via outcome blinding breaks and access to the PERFORM intervention by control group, assessed by asking research staff to keep a log of blind breaks and by asking patients in the control group as part of their follow-up assessment whether they had accessed/been exposed to any aspects of the PERFORM intervention at 3 months

## **Completion date**

16/05/2024

## **Eligibility**

### **Key inclusion criteria**

Current exclusion criteria as of 24/07/2023:

1. Adults  $\geq 18$  years old
2. Able and willing to provide informed consent
3. To be mobile (including the use of walking aids)
4. 2 or more long terms conditions from the lists below– with at least one LTC identified from work package 1 as having evidence of the beneficial benefits of exercise. The data identified that individuals must have a diagnosis of at least one of the following:
  - 4.1. Arthritis
  - 4.2. Asthma
  - 4.3. Atrial fibrillation
  - 4.4. Bronchiectasis

- 4.5. Cancer
- 4.6. Chronic kidney disease
- 4.7. Chronic obstructive pulmonary disease (COPD)
- 4.8. Connective tissue disease (pain)
- 4.9. Coronary heart disease
- 4.10. Dementia
- 4.11. Depression
- 4.12. Diabetes mellitus
- 4.13. Heart failure
- 4.14. Hypertension
- 4.15. Long-COVID
- 4.16. Multiple sclerosis
- 4.17. Osteoporosis
- 4.18. Painful condition
- 4.19. Parkinson's disease
- 4.20. Peripheral vascular disease
- 4.21. Polycystic ovarian syndrome
- 4.22. Psychoactive substance misuse
- 4.23. Stroke or transient ischaemic attack
- 4.24. Patients could also have one of the following conditions from the list below:
- 4.25. Anorexia nervosa or bulimia
- 4.26. Anxiety
- 4.27. Atrial fibrillation
- 4.28. Chronic fatigue syndrome
- 4.29. Chronic liver disease
- 4.30. Chronic sinusitis
- 4.31. Diverticular disease
- 4.32. Endometriosis
- 4.33. Epilepsy
- 4.34. Glaucoma
- 4.35. Inflammatory bowel disease
- 4.36. Irritable bowel syndrome
- 4.37. Meniere's disease
- 4.38. Migraines
- 4.39. Pernicious anaemia
- 4.40. Prostate disorders
- 4.41. Psoriasis or eczema
- 4.42. Schizophrenia or bipolar affective disorder
- 4.43. Thyroid disease
- 4.44. Treated constipation
- 4.45. Treated dyspepsia
- 4.46. Viral hepatitis

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5. The data identified that individuals must have a diagnosis of at least one of the following:

- 5.1. Arthritis
- 5.2. Asthma
- 5.3. Atrial fibrillation
- 5.4. Bronchiectasis
- 5.5. Cancer
- 5.6. Chronic kidney disease
- 5.7. Chronic obstructive pulmonary disease
- 5.8. Connective tissue disease (pain)
- 5.9. Coronary heart disease
- 5.10. Dementia
- 5.11. Depression
- 5.12. Diabetes mellitus
- 5.13. Heart failure
- 5.14. Hypertension
- 5.15. Long-COVID
- 5.16. Multiple sclerosis
- 5.17. Osteoporosis
- 5.18. Painful condition
- 5.19. Parkinson's disease
- 5.20. Peripheral vascular disease
- 5.21. Polycystic ovarian syndrome
- 5.22. Psychoactive substance misuse
- 5.23. Stroke or transient ischaemic attack

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

60

**Key exclusion criteria**

Current exclusion criteria as of 24/07/2023:

1. Unable to give consent for the study
2. Unable to communicate in English (carer or support worker may be available)
3. Known contraindications to exercise (as defined by the American College of Sports Medicine)
4. ("ACSM's guidelines for exercise testing and prescription 11th Ed. 2021.") to include:
  - 4.1. Unstable cardiac disease

- 4.2. Current fever
- 4.3. Significant aortic aneurysm (more than 5.5 cm)
5. Unable to attend in-person training sessions
6. Participation in a exercised rehabilitation programme in the last 6 months.
7. Unstable psychiatric disorder that limits or disrupts group based interventions.
8. On an End of Life pathway with a prognosis of less than 12 months survival.
9. Active malignancy (on chemotherapy/radiotherapy/planned urgent surgery)
10. 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.
11. Pregnant women
12. Under 18's
13. Living in a Nursing Home.
14. Unsafe to exercise in a group without 1:1 supervision (e.g. significant risk of falls)

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3. Known contraindications to exercise (as defined by the American College of Sports Medicine) ("ACSM's guidelines for exercise testing and prescription 9th Ed. 2014.") to include:
  - 3.1. Unstable cardiac disease
  - 3.2. Current fever
  - 3.3. Significant aortic aneurysm (more than 5.5 cm)
4. Unable to attend in-person training sessions
5. Unstable psychiatric disorder that limits or disrupts group-based interventions
6. On an End of Life pathway with a prognosis of fewer than 12 months of survival
7. Active malignancy (on chemotherapy/radiotherapy/planned urgent surgery)
8. 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
9. Pregnant women
10. Aged under 18 years old
11. Living in a nursing home
12. Unsafe to exercise in a group without 1:1 supervision (e.g. significant risk of falls)

**Date of first enrolment**

06/09/2023

**Date of final enrolment**

23/01/2024

## **Locations**

**Countries of recruitment**

United Kingdom

England

Wales

**Study participating centre**  
**University Hospitals of Leicester NHS Trust**  
Leicester Royal Infirmary  
Infirmary Square  
Leicester  
United Kingdom  
LE1 5WW

**Study participating centre**  
**Freeman Road Hospital**  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**  
**The Reach for Health Centre**  
Stefen Hill  
Stefen Hill Ground  
Western Ave  
Daventry  
United Kingdom  
NN11 4UD

## **Sponsor information**

**Organisation**  
University of Leicester

**ROR**  
<https://ror.org/04h699437>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**

National Institute for Health and Care Research

### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available for sharing via controlled access by authorised University of Leicester staff (as delegated by the trial sponsor) and anonymised IPD within the clinical trial dataset will be available for sharing via open access after the trial is published.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		17/09/2025	23/09/2025	Yes	No
<a href="#">Results article</a>	Process evaluation	17/09/2025	23/09/2025	Yes	No
<a href="#">Protocol article</a>		05/04/2024	30/06/2025	Yes	No
<a href="#">HRA research summary</a>			20/09/2023	No	No
<a href="#">Protocol file</a>	version 2.0	16/05/2023	20/12/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes