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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
22/02/2023		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
24/05/2023	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
23/09/2025	Other			

#### 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** 

#### ORCID ID

https://orcid.org/0000-0002-9834-0366

#### Contact details

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# Type(s)

**Public** 

#### Contact name

Ms Gwen Barwell

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PERFORMLCTU@leicester.ac.uk

# 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.

#### Previous interventions:

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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 ≥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**

#### Kev inclusion criteria

Current exclusion criteria as of 24/07/2023:

- 1. Adults ≥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

#### Previous inclusion criteria:

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- 2. Able and willing to provide informed consent
- 3. To be mobile (including the use of walking aids)
- 4. Two or more long terms conditions (LTC), with at least one LTC identified from work package 1 as having evidence of the beneficial benefits of exercise

- 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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- 1. Unable to give consent for the study
- 2. Unable to communicate in English (carer or support worker may be available)
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- 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 Results article	Details		<b>Date added</b> 23/09/2025	<b>Peer reviewed?</b> Yes	<b>Patient-facing?</b> No
Results article	Process evaluation	17/09/2025	23/09/2025	Yes	No
Protocol article		05/04/2024	30/06/2025	Yes	No
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.0	16/05/2023	20/12/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes