ISRCTN68786622 https://doi.org/10.1186/ISRCTN68786622

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

Submission date	**Recruitment status**	[X] Prospectively registered
22/02/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/05/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/06/2025	Other	[X] Record updated in last year

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

Study website
https://le.ac.uk/perform

Contact information

Type(s)
Principal Investigator

Contact name
Prof Sally Singh

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
321067

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other, Quality of life

Participant information sheet
No participant information sheet available

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 measure
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)

Secondary outcome measures
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

Overall study start date
01/01/2023

Completion date

16/05/2024

Eligibility

Key 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

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Previous inclusion criteria:

1. Adults ≥18 years old
2. Able and willing to provide informed consent
3. To be mobile (including the use of walking aids)
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5. The data identified that individuals must have a diagnosis of at least one of the following:
5.1. Arthritis
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5.4. Bronchiectasis
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5.6. Chronic kidney disease
5.7. Chronic obstructive pulmonary disease
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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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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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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) ("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
England

United Kingdom

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
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Daventry
United Kingdom
NN11 4UD

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Sponsor type
University/education

Website
http://www.le.ac.uk/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/01/2025

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?
HRA research summary			20/09/2023	No	No
Protocol file	version 2.0	16/05/2023	20/12/2023	No	No
Protocol article		05/04/2024	30/06/2025	Yes	No