

# Personalised exercise rehabilitation for people with multiple long-term conditions: Main Trial

<b>Submission date</b> 07/08/2024	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 10/10/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/02/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 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.

In this trial, we will be testing a personalised exercise-based rehabilitation programme called PERFORM. This was developed with patients and clinicians to specifically meet the needs of people with multiple long-term conditions. 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.

The PERFORM Feasibility study was registered at ISRCTN: <https://www.isrctn.com/ISRCTN68786622>

### 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. The trial is looking for participants who are not currently eligible for standard cardiac or pulmonary rehabilitation to go into the randomised controlled trial, and for participants who ARE eligible for standard cardiac or pulmonary rehabilitation to go into the prospective cohort study.

### What does the study involve?

All participants will be asked to attend an initial (baseline) research visit and a 3-month and 12-month follow-up visit.

These visits will take place at their local hospital or rehabilitation clinic and take about 2-3 hours to complete. They will include physical assessment measures such walking tests and handgrip strength. In the randomised controlled trial participants will be randomly allocated to either

take part in the PERFORM exercise rehabilitation programme or continue with their usual care. Participants in the prospective cohort study will receive the PERFORM exercise rehabilitation instead of standard cardiac or pulmonary rehabilitation.

After participants have been randomised, if they are in a social media site they will be given the link to access a PERFORM Facebook group.

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.

Participants who take part in the social media group will also have the opportunity to take part in an interview that includes their thoughts on the Facebook group, the pros and cons of using social media 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 2024 to July 2027

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

## Contact information

### Type(s)

Scientific, Principal investigator

### Contact name

Prof Sally Singh

### ORCID ID

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

### Contact details

Department of Respiratory Science  
Biomedical Research Centre  
University of Hospitals of Leicester NHS Trust

Leicester  
United Kingdom  
LE3 9QP  
+44 (0)116 229 7309  
sally.singh@uhl-tr.nhs.uk

### **Type(s)**

Public

### **Contact name**

Ms Gwen Barwell

### **Contact details**

Leicester Clinical Trials Unit  
Maurice Shock Building  
University of Leicester  
Leicester  
United Kingdom  
LE1 7RH  
+44 116 223 1202  
performlctu@leicester.ac.uk

## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

340399

### **Protocol serial number**

1006, CPMS 62643

## **Study information**

### **Scientific Title**

Personalised exercise rehabilitation for people with multiple long-term conditions: Randomised Controlled Trial with Prospective Cohort Study and social media SWAT

### **Acronym**

PERFORM Main Trial

### **Study objectives**

Patients with two or more long-term conditions who complete the PERFORM Exercise Rehabilitation Programme will have a greater improvement in their overall health, compared to patients randomised into the standard-of-care control group.  
Participants who are given access to the PERFORM Facebook group are more likely to stay in the study until the end and to engage with it.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 02/12/2024, South Central - Berkshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8012; berkshireb.rec@hra.nhs.uk), ref: 24/SC/0318

### **Study design**

Multi-centre randomized controlled trial with prospective cohort study and social media SWAT

### **Primary study design**

Interventional

### **Study type(s)**

Other, Quality of life

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

Multiple long-term conditions

### **Interventions**

The PERFORM study is a concurrent multicentre superiority RCT and prospective cohort study with embedded process and economic evaluations. The trial includes an additional study within a trial (SWAT) to test if providing study patients access to social media will improve their retention in the study. Study sites will be allocated 1:1 prior to recruitment to be social media sites or control sites.

In the RCT, participants will be randomised to intervention (PERFORM rehabilitation programme + usual care) or control (usual care alone).

In the PCS, participants will all receive the PERFORM rehabilitation programme.

All participants will have a baseline assessment visit, a 3-month follow-up visit and a 12-month follow-up visit.

The PERFORM rehabilitation programme intervention takes place in between the baseline visit and 3-month follow-up.

The PERFORM intervention comprises of an 8 week supervised rehabilitation programme with sessions twice a week (16 sessions total). Each session will last for 2 hours (1hr of exercise, and 1hr patient 'Health and Wellbeing' self-care support session and Q&A/opportunity). The intervention will be offered within 4 weeks of randomisation.

Each exercise session will offer an individually prescribed and progressed aerobic walking programme (a combination of walking (treadmill where available) and strength and resistance training. Participants will also be encouraged to complete a home exercise programme and a progress tracker.

The 'Health and Wellbeing' self-care support sessions will offer advice and support for behaviour change to support positive lifestyle changes and symptom management. Much of the advice will be appropriate to all participants, but there will also be packages of advice that will only be specific to certain groups. The information will be supplemented by written leaflets and material to support the individual to share with their family and carers.

Participants in the social media sites will be offered a link to a closed and secure Facebook group offering peer support and trial materials. There will be 2 separate groups, one for participants in the intervention arm and one for usual care participants

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Health related quality of life using the EQ-5D-5L at 3 month follow-up.

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

Measured at the 3-month and 12-month follow-up visits.

1. HRQoL: EuroQoL (EQ-5D-5L) VAS
2. Exercise/functional capacity: incremental shuttle walk test (ISWT)
3. Endurance Shuttle Walk Test
4. 4 Metre Gait Speed (MGS)
5. Strength: Hand Grip Strength
6. Mood: Patient Health Questionnaire-9 (PHQ-9)
7. Generalised Anxiety Disorder Assessment-7 (GAD-7)
8. Physical activity: International Physical Activity Questionnaire (IPAQ)
9. Frailty: Functional Assessment of Chronic Illness Therapy; Fried Exhaustion and Weight Loss
10. Fatigue (FACIT-F)
11. Pain: Brief Pain Inventory (BPI)
12. Breathlessness: Dyspnoea-12
13. Sleep: Medical Outcome Study Sleep Scale (MOS Sleep Scale)
14. Multimorbidity Treatment Burden Questionnaire (MTBQ)
15. ICEpop CAPability Measures for Adults (ICECAP-A)
16. Exercise adherence: Exercise Adherence Rating Scale (EARS)
17. Hospitalisations and overnight hospital admissions at 12 months
18. Clinical events – mortality, primary care contacts, and social and healthcare utilisation including medication

## **Completion date**

06/07/2027

## **Eligibility**

### **Key inclusion criteria**

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. Breathlessness symptoms when hurrying on level ground or walking up a slight hill (adapted from MRC 2 or above)
5. 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:
  - 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 (COPD)
  - 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
- 5.24. Patients could also have one of the following conditions from the list below:
- 5.25. Anorexia nervosa or bulimia
- 5.26. Anxiety
- 5.27. Chronic fatigue syndrome
- 5.28. Chronic liver disease
- 5.29. Chronic sinusitis
- 5.30. Diverticular disease
- 5.31. Endometriosis
- 5.32. Epilepsy
- 5.33. Glaucoma
- 5.34. Inflammatory bowel disease
- 5.35. Irritable bowel syndrome
- 5.36. Meniere's disease
- 5.37. Migraines
- 5.38. Pernicious anaemia
- 5.39. Prostate disorders
- 5.40. Psoriasis or eczema
- 5.41. Schizophrenia or bipolar affective disorder
- 5.42. Thyroid disease
- 5.43. Treated constipation
- 5.44. Treated dyspepsia
- 5.45. Viral hepatitis

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

## **Key exclusion criteria**

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) ("ACSM's guidelines for exercise testing and prescription 11th Ed. 2021.") 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. Participation in an exercise rehabilitation programme in the last 6 months
6. Unstable psychiatric disorder that limits or disrupts group-based interventions
7. On an End of Life pathway with a prognosis of less than 12 months survival
8. Active malignancy (on chemotherapy/radiotherapy/planned urgent surgery)
9. 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
10. Pregnancy
11. Under 18's
12. Living in a Nursing Home.
13. Unsafe to exercise in a group without 1:1 supervision (e.g. significant risk of falls, significant psychiatric issues)
14. Greater than 80% predicted on the ISWT at initial assessment

## **Date of first enrolment**

14/02/2025

## **Date of final enrolment**

06/07/2026

## **Locations**

### **Countries of recruitment**

United Kingdom

England

Scotland

### **Study participating centre**

**University Hospitals of Leicester NHS Trust**

Leicester Royal Infirmary

Infirmary Square

Leicester

United Kingdom

LE1 5WW

### **Study participating centre**

**The Newcastle upon Tyne Hospitals NHS Foundation Trust**

Freeman Hospital  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**

**Reach for Health**

Stefen Hill, Stefen Hill Ground, Western Ave,  
Daventry  
United Kingdom  
NN11 4UD

**Study participating centre**

**York and Scarborough Teaching Hospitals NHS Foundation Trust**

York Hospital  
Wigginton Road  
York  
United Kingdom  
YO31 8HE

**Study participating centre**

**Cornwall Partnership NHS Foundation Trust**

Carew House  
Beacon Technology Park  
Dunmere Road  
Bodmin  
United Kingdom  
PL31 2QN

**Study participating centre**

**Healthworks Newcastle**

Health Resource Centre  
Adelaide Terrace  
Newcastle upon Tyne  
United Kingdom  
NE4 8BE

**Study participating centre**

**Heart Care Wallsall**

12 Portland St,  
Walsall  
United Kingdom  
WS2 8AB

**Study participating centre**

**University of Bedfordshire**

University Square  
Luton  
United Kingdom  
LU1 3JU

**Study participating centre**

**Livewell Southwest**

Local Care Centre  
200 Mount Gould Road  
Plymouth  
United Kingdom  
PL4 7PY

**Study participating centre**

**Herefordshire and Worcestershire Health and Care NHS Trust**

Unit 2 Kings Court  
Charles Hastings Way  
Worcester  
United Kingdom  
WR5 1JR

**Study participating centre**

**Wave Leisure Lewes**

Mountfield Rd,  
Lewes  
United Kingdom  
BN7 2XG

**Study participating centre**

**Body Happy Lewes**

40 Friars Walk,

Lewes  
United Kingdom  
BN7 2LG

**Study participating centre**  
**University of Glasgow**  
University Avenue  
Glasgow  
United Kingdom  
G12 8QQ

## 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 available from the corresponding author on reasonable request  
PERFORMLCTU@leicester.ac.uk

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version 1.0	07/08/2024	08/08/2024	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes