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

Submission date
07/08/2024

Recruitment status
Recruiting

Registration date
10/10/2024

Overall study status
Ongoing

Last Edited
25/09/2026

Condition category
Other

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[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 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 April 2028.

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

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Public

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Additional identifiers

Integrated Research Application System (IRAS)
340399

Central Portfolio Management System (CPMS)
62643

Protocol serial number
1006

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

Primary study design
Interventional

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

Study type(s)
Quality of life, Other

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
30/04/2028

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 25/09/2026:

1. Adults ≥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
If participant only has one condition from the specified list, they must have at least one other diagnosed long-term health condition

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Previous key 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)
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
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

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
30/04/2027

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton

Newcastle upon Tyne
England
NE7 7DN

Study participating centre
Reach for Health
Stefen Hill, Stefen Hill Ground, Western Ave,
Daventry
England
NN11 4UD

Study participating centre
York and Scarborough Teaching Hospitals NHS Foundation Trust
York Hospital
Wigginton Road
York
England
YO31 8HE

Study participating centre
Cornwall Partnership NHS Foundation Trust
Carew House
Beacon Technology Park
Dunmere Road
Bodmin
England
PL31 2QN

Study participating centre
Healthworks Newcastle
Health Resource Centre
Adelaide Terrace
Newcastle upon Tyne
England
NE4 8BE

Study participating centre
Heart Care Wallsall
12 Portland St,

Walsall
England
WS2 8AB

Study participating centre
University of Bedfordshire
University Square
Luton
England
LU1 3JU

Study participating centre
Herefordshire and Worcestershire Health and Care NHS Trust
Unit 2 Kings Court
Charles Hastings Way
Worcester
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WR5 1JR

Study participating centre
University of Glasgow
University Avenue
Glasgow
Scotland
G12 8QQ

Study participating centre
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Bournemouth
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BH5 2DF

Study participating centre
North Tees and Hartlepool NHS Foundation Trust
University Hospital of Hartlepool
Holdforth Road
Hartlepool
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TS24 9AH

Study participating centre
Lincolnshire Community Health Services NHS Trust
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Waterside South
Lincoln
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LN5 7JH

Study participating centre
Cardiff Metropolitan University
Po Box 377
Llandaff
Cardiff
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CF5 2SG

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
England
S5 7AU

Study participating centre
Mid Yorkshire Teaching NHS Trust
Pinderfields Hospital
Aberford Road
Wakefield
England
WF1 4DG

Study participating centre
Sussex Community NHS Foundation Trust
Brighton General Hospital
Elm Grove
Brighton
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Study participating centre
Heartbeat (Preston)
Sir Tom Finney Way
Preston
England
PR1 6PA

Study participating centre
Central London Community Healthcare NHS Trust
Ground Floor
15 Marylebone Road
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NW1 5JD

Study participating centre
Liverpool John Moores University
Rodney House 70
Mount Pleasant
Liverpool
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L3 5UX

Study participating centre
Dartford and Gravesham NHS Trust
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Darenth Wood Road
Dartford
England
DA2 8DA

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?
Protocol file	version 1.0	07/08/2024	08/08/2024	No	No
Protocol file	version 5.0	03/02/2026	25/09/2026	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes