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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
17/02/2025

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 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

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

Contact information

Type(s)
Scientific, Principal Investigator

Contact name
Prof Sally Singh

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
340399

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Fitness/sport facility, Hospital

Study type(s)
Other, Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

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

Secondary outcome measures
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

Overall study start date
05/01/2024

Completion date
06/07/2027

Eligibility

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
906

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
England

Scotland

United Kingdom

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
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PL31 2QN

Study participating centre
Healthworks Newcastle
Health Resource Centre
Adelaide Terrace
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United Kingdom
NE4 8BE

Study participating centre
Heart Care Wallsall
12 Portland St,
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WS2 8AB

Study participating centre
University of Bedfordshire
University Square
Luton
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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
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BN7 2XG

Study participating centre
Body Happy Lewes
40 Friars Walk,
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BN7 2LG

Study participating centre
University of Glasgow
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Sponsor information

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Sponsor type
University/education

Website
https://www.nhs.uk/Services/hospitals/Services/Service/DefaultView.aspx?id=288606

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 publications in a high-impact peer-reviewed journal

Intention to publish date
01/05/2029

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