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Supervised Pulmonary Hypertension Exercise REhabilitation (SPHERe) trial

Submission date
13/03/2019

Recruitment status
No longer recruiting

Registration date
18/03/2019

Overall study status
Completed

Last Edited
22/07/2024

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Pulmonary hypertension is a disabling long-term condition that can greatly reduce quality of life. Blood vessels supplying the lungs become thick and stiff, restricting blood flow. Blood pressure is increased in these vessels meaning the heart must work harder to pump blood to the lungs. Over time, the heart may begin to fail. Breathlessness, fatigue and dizziness are the most common symptoms. People with pulmonary hypertension are often anxious about carrying out normal daily activities. There are five types of pulmonary hypertension with different causes. Medical treatment is different for each type, and may help to improve symptoms. Little is known about whether exercise rehabilitation may help people living with pulmonary hypertension. Supervised exercise rehabilitation is a common treatment for many heart and lung conditions. It can improve fitness, breathlessness, anxiety, depression, and quality of life. Some research has shown that exercise rehabilitation may be helpful for people with certain types of pulmonary hypertension: pulmonary arterial hypertension, and pulmonary hypertension due to blood clots in the lungs. Most of these exercise programmes included three weeks of intensive exercise as a hospital in-patient. This is not feasible in the NHS, where exercise rehabilitation is an outpatient service, typically lasting an hour, twice a week for eight weeks. It is not known whether outpatient/home-based exercise rehabilitation can help improve the lives of people with pulmonary hypertension. The aim of this study is to find out whether outpatient exercise rehabilitation, combined with psychological and motivational support, can improve fitness and quality of life for people living with pulmonary hypertension, particularly people whose pulmonary hypertension is secondary to heart or lung disease, because exercise rehabilitation has not been researched in these groups. The study will be run in specialist rehabilitation centres by staff experienced in treating people with heart and lung problems.

COVID-19 update (29/03/2021):
In light of the COVID-19 pandemic, exercise rehabilitation will move to an online home-based delivery model. We have drawn on existing resources and data from home-based rehabilitation programmes aimed at breathless, fatigued and anxious clinical populations, where data supports the potential efficacy of home-based vs centre-based programmes. SPHERe will now be resource-based (manual, online content) using functional (body weight or chair-based) exercise and a structured home-based exercise bike programme, remotely supervised and facilitated online by trained practitioners.

Who can participate?
Patients with pulmonary hypertension who live near one of at least 10 rehabilitation centres mainly in the East and West Midlands

What does the study involve?
Participants will be randomly allocated to either remotely supervised exercise with psychological and motivational support, or best-practice usual care (general physical activity advice). The 8-week intervention includes:
1. An online individual assessment and exercise familiarisation session
2. Once-weekly live online remotely supervised group home exercise programme
3. Twice-weekly guided home exercise bike and functional fitness programme
4. Weekly group online psychosocial and motivational support and education session (for 6 weeks).
People in the usual care group will receive a single (online) session of 1:1 advice on safe and effective lifestyle physical activity. A walking test and quality of life questionnaires will be used over 1 year to measure if the intervention can help people with pulmonary hypertension, and represents good value for the NHS.

What are the possible benefits and risks of participating?
This study may not offer people any direct benefit, but the results will help people with pulmonary hypertension in the future. If any of the assessments find anything unusual with participants' health, they will receive prompt and appropriate medical care and attention. Exercise carries a very small risk of complications for people with pulmonary hypertension. If it is likely that certain people will have a problem during exercise, their medical team will not ask them to take part. For people who do take part, remote supervision will be provided by specialist staff. Exercise is likely to cause some tiredness, breathlessness and sore muscles, but this should get a bit easier over time. The researchers do not anticipate any serious risk to participants.

Where is the study run from?
University Hospitals Coventry & Warwickshire NHS Trust (UK)

When is the study starting and how long is it expected to run for?
June 2019 to August 2024

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
261218

Protocol serial number
HTA 17/129/02

Study information

Scientific Title
Supervised Pulmonary Hypertension Exercise REhabilitation (SPHERe): a multi-centre randomized controlled trial

Acronym
SPHERe

Study objectives
The SPHERE intervention will improve clinical and patient-reported outcomes when compared to best practice usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/07/2019, West Midlands - Coventry & Warwickshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0)2071048101; nrescommittee.westmidlands-coventryandwarwick@nhs.net), REC ref: 19/WM/0155

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied

Pulmonary hypertension

Interventions
Current interventions as of 29/03/2021:
Participants will be randomly allocated to either remotely supervised exercise with psychological and motivational support, or best-practice usual care (general physical activity advice).

The intervention group will be invited to complete 8 weeks of once-weekly remotely supervised exercise rehabilitation, alongside a home exercise bike programme (twice-weekly). The researchers have developed an exercise programme suitable for people with all types of pulmonary hypertension that can be delivered virtually from existing NHS exercise rehabilitation services. The study will be run from specialist rehabilitation centres by staff experienced in treating people with heart and lung problems. Weekly psychological and motivational support aims to reduce anxiety and improve exercise adherence.

People in the usual care group will receive a single (online) session of 1:1 advice on safe and effective lifestyle physical activity, but not take part in the exercise programme.

Previous interventions:
Participants are randomly allocated to either supervised exercise with psychological and motivational support, or to continue with usual care (general physical activity advice).

The intervention group will be invited to complete 8 weeks of twice-weekly supervised outpatient exercise rehabilitation. The researchers have developed an exercise programme suitable for people with all types of pulmonary hypertension that can be delivered within existing NHS exercise rehabilitation services. They have tested, evaluated, and refined this over a six-month period. The study will be run in specialist rehabilitation centres by staff experienced in treating people with heart and lung problems. Psychological and motivational support will help reduce anxiety and improve exercise adherence.

People in the usual care group will receive general physical activity advice, but not supervised exercise.

Intervention Type
Behavioural

Primary outcome(s)
Exercise capacity measured with incremental shuttle walk test (ISWT) at 4 months.

Key secondary outcome(s))
Current secondary outcome measures as of 24/02/2023:
1. Disease-specific health-related quality of life (HR-QoL) measured with Cambridge Pulmonary Hypertension Outcome Review at 4 and 12 months
2. Health utility measured with EQ-5D-5L at 4 and 12 months
3. Emotional well-being measured with the Hospital Anxiety and Depression Scale at 4 and 12 months
4. Generalised self-efficacy measured with a psychometric scale at 4 and 12 months
5. Fatigue measured with the Fatigue Severity Scale at 4 and 12 months
6. Functional status measured using WHO functional class at 4 and 12 months
7. Self-reported medication use at 4 and 12 months

8. Time to clinical worsening measured by medical notes and discussion with a clinician at 4 and 12 months
9. Health and social care resource use measured by participant self-report and NHS data at 4 and 12 months
10. All-cause hospital admissions from GP records at 12 months
11. Adverse events measured with NHS data at 4 and 12 months
12. All-cause mortality

Previous secondary outcome measures as of 29/03/2021 to 24/02/2023:
1. Exercise capacity measured with incremental shuttle walk test at 12 months
2. Disease-specific health-related quality of life (HR-QoL) measured with Cambridge Pulmonary Hypertension Outcome Review at 4 and 12 months
3. Emotional well-being measured with the Hospital Anxiety and Depression Scale at 4 and 12 months
4. Self-efficacy measured with the Generalised self-efficacy scale at 4 and 12 months
5. Fatigue measured with the Fatigue Severity Scale at 4 and 12 months
6. Functional status measured using WHO functional class at 4 and 12 months
7. Self-reported medication use at 4 and 12 months
8. Time to clinical worsening measured by medical notes and discussion with clinician at 4 and 12 months
9. Hospital admissions measured with NHS data at 4 and 12 months
10. Adverse events measured with NHS data at 4 and 12 months
11. All-cause mortality measured with NHS data at 4 and 12 months
12. Heath utility measured with EQ-5D-5L at 4 and 12 months
13. Health and care resource use measured by participant self-report and NHS records at 4 and 12 months.

Previous secondary outcome measures:
1. Exercise capacity measured with incremental shuttle walk test at 12 months
2. Exercise capacity measured with six-minute walk test at 4 and 12 months
3. Disease-specific health-related quality of life (HR-QoL) measured with Cambridge Pulmonary Hypertension Outcome Review at 4 and 12 months
4. Emotional well-being measured with the Hospital Anxiety and Depression Scale at 4 and 12 months
5. Self-efficacy measured with the Generalised self-efficacy scale at 4 and 12 months
6. Fatigue measured with the Fatigue Severity Scale at 4 and 12 months
7. Functional status measured using WHO functional class at 4 and 12 months
8. Medication use measured by self- report case report form at 4 and 12 months
9. Time to clinical worsening measured by medical notes and discussion with clinician at 4 and 12 months
10. Hospital admissions measured with NHS data at 4 and 12 months
11. Adverse events measured with NHS data at 4 and 12 months
12. All-cause mortality measured with NHS data at 4 and 12 months
13. Heath utility measured with EQ-5D-5L at 4 and 12 months
14. Health and care resource use measured by participant self-report and NHS records at 4 and 12 months

Completion date
31/08/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 29/03/2021:
1. Adults with confirmed PH (groups 1 to 5) as detailed in ESC/ERS guidelines
2. Clinically stable
3. World Health Organisation (WHO) functional class II, III or IV
4. Fluent in spoken English to allow engagement with intervention and physical outcome measures
5. Live within reasonable travelling distance (as defined by the participant) of a SPHERE exercise rehabilitation centre (outcome assessments only)
6. Ability to provide informed consent
7. Access to appropriate IT infrastructure (computer, laptop, tablet, smart phone, email and internet connection)
8. Ability to make suitable travel arrangements to attend clinic (outcome assessments only)

Previous inclusion criteria:
1. Adults with confirmed PH (groups 1 to 5) as detailed in ESC/ERS guidelines
2. Clinically stable
3. World Health Organisation (WHO) functional class II, III or IV
4. Fluent in spoken English to allow engagement with intervention and physical outcome measures
5. Live within reasonable travelling distance (as defined by the participant) of a SPHERE exercise rehabilitation centre
6. Ability to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
153

Key exclusion criteria
Current exclusion criteria as of 29/03/2021:
1. Absolute contraindications to exercise as per international clinical guidelines
2. PH related complications, or comorbidities severe enough to prevent attendance at a SPHERE centre, or participation in exercise rehabilitation
3. Any mental health issue that will prevent engagement with study procedures
4. Previous randomisation in the present trial
5. Pregnancy at the time of recruitment

Previous exclusion criteria:
1. Absolute contraindications to exercise as per international clinical guidelines
2. PH related complications, or comorbidities severe enough to prevent attendance at a SPHERE

centre, or participation in exercise rehabilitation
3. Any mental health issue that will prevent engagement with study procedures
4. Unable to make suitable travel arrangements
5. Previous randomisation in the present trial
6. Pregnancy

Date of first enrolment
16/06/2021

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
University Hospitals Coventry & Warwickshire NHS Trust
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Walsall Healthcare NHS Trust
Manor Hospital
Moat Road
Walsall
United Kingdom
WS2 9PS

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Broomfield Hospital
Court Road
Broomfield
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
Golden Jubilee National Hospital
Agamemnon Street
Clydebank
United Kingdom
G81 4DY

Sponsor information

Organisation
University Hospitals Coventry & Warwickshire NHS Trust

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

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 will be available upon request after publication of the main study results. Requests for data sharing will be managed in accordance with University of Warwick policy on data sharing.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/05/2020	26/05/2020	Yes	No
Protocol article	Protocol update	20/07/2024	22/07/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	version 1.1	01/05/2024	12/07/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes