

We are inviting you to take part in a research study

- Before you decide if you want to take part, it is important to understand why the study is being done and what it will involve.
- Please take time to read this information carefully. Discuss it with friends and relatives.
- You are free to decide if you want to take part. If you choose not to take part, the treatment you receive will not be affected.
- If you decide to take part, you can withdraw from the study at any time.
- If anything is unclear, or you would like more information, please just ask us.

Important things you need to know

- We want to know which of two treatments is better at helping people with pulmonary hypertension.
- The study has two groups and people in each group receive a different treatment. People in the first group will have a single online advice session with an exercise specialist. People in the second group will take part in an online exercise programme. We are comparing people across these two groups.
- Complications during exercise are very rare but could be serious.
- If you decide to take part, you will need to visit a local rehabilitation centre three times over one year for SPHERE assessments. You will be reimbursed for your travel.
- The study will help us to understand if the NHS should provide exercise rehabilitation for people with pulmonary hypertension.

What's in this leaflet?

- Why are we doing this study?
- Why have I been asked to take part?
- Do I have to take part?
- What does taking part in this study involve?
- What are the benefits and risks of taking part?
- What will we do with your personal information?
- How to contact us

FUNDED BY

NIHR | National Institute for Health and Care Research

This study is funded by the National Institute for Health Research (NIHR) HTA programme (project number 17/129/02). The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

How to contact us

If you have any questions about this study, please contact:

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Tel: 02476 234 570
stuart.ennis@warwick.ac.uk

Why are we doing this study?

Exercise rehabilitation can be very helpful for people with a range of different heart and lung conditions, often improving breathing and fitness. We would like to find out which of two study treatments is better at helping people with pulmonary hypertension.

Why have I been asked to take part?

We are asking you to take part in this study because you have pulmonary hypertension. We will be asking 352 people in total, in England and Scotland, to take part. There is a chance you may receive more than one invitation letter. This might happen if you are being cared for by different hospitals or healthcare providers.

Do I have to take part?

It is up to you to decide if you want to take part. If you agree to take part, we will ask you to complete a consent form. Even after completing the consent form, you can withdraw at any time without giving a reason. If you don't take part, or you withdraw, the standard of care you receive will not be affected. If you decide to withdraw, we will keep the information about you that we have already collected. We will also continue to collect information about your health from your GP and NHS records, if you have consented to this. If you do not want this to happen, please tell us and we will stop.

What does taking part in this study involve?

Telephone assessment

If you are interested in taking part, please complete the expression of interest form and send it back to the SPHERE team in the pre-paid envelope provided. A member of the team will then contact you by telephone to ask you some questions and check your suitability to take part in the study. If you might be suitable, you will be invited to attend an assessment at a local rehabilitation centre. You will also be sent a questionnaire in the post for you to complete and take to the assessment. The questionnaire asks about how pulmonary hypertension affects your life, and how often you use healthcare services. It will take about 30 minutes to complete.

Suitability check and consent to take part

The baseline assessment at a local rehabilitation centre will be with an exercise specialist and will last around 30 minutes. At this appointment, you will be asked some further questions to confirm your suitability to take part in the study. If so, you will be asked to complete and sign a consent form. Once you have done this, we will ask you to complete a questionnaire. During the COVID-19 pandemic we may send this questionnaire to you in the post for you to complete before your appointment and ask you to bring this to your appointment. If you are not suitable to take part, we will ask you to take the completed questionnaire back home for you to destroy.

Walking test

As part of the assessment, we will ask you to complete a walking test so we can find out which treatment best helps people's fitness. We will ask you to walk for up to ten minutes between two cones, 10 metres

(about 30 feet) apart, guided by some beeps. The idea is to walk from one cone to the other, arriving just as the next beep sounds. This begins very slowly, but gradually the beeps become closer together, so you have to walk a bit faster. The test ends when the beeps are so close together that you don't make it to the other end before the next beep sounds. You will probably get out of breath and feel warm.

We will also ask you to attend two further assessments- one at four months and one at twelve months. At these appointments you will be asked to repeat the walking test and you will be given a paper questionnaire to complete. We may ask you to keep a record of how many times you use NHS services between your assessments in order to help you complete the questionnaires. During the COVID-19 pandemic we may ask you to complete this questionnaire at home and return to the SPHERE team in a pre-paid envelope.

Study groups

After you have completed your first questionnaire and walking test, you will be assigned by chance (randomised) to one of two groups:

- 1) A single online session of exercise advice and support.

OR

- 2) An 8 week online exercise and support programme.

You or the research team will not be able to choose which group you are in. This will be decided by a computer at random, just like tossing a coin.

With your permission, we will contact your GP to let them know you are taking part in the study. If you do not want us to tell your GP, you will not be able to take part.

COVID-19

Because of the COVID-19 pandemic, we are taking extra precautions to keep people who are helping us with our research as safe as possible. Our exercise specialists will wear an appropriate level of personal protective equipment (PPE) including a face covering. Social distancing will be maintained at all times and the room and equipment used will be cleaned in line with current infection control measures.

If you are not able to come to the rehabilitation centre by car, you can use public transport at your own risk. Alternatively, a taxi can be arranged to get you to and from the assessment. We will ask both you and the driver to wear a face covering. Measures will be in place to maximise your health and safety whilst you travel.

What will I have to do next?

Depending on which group you are assigned to, we will ask you to do different things:

Group 1: Single online session of advice and support

1. A half-hour long individual appointment with a SPHERE exercise specialist via telephone or video call.
2. Take part in simple activities that you can do safely at home for which we will provide written information.
3. Continue with your life and usual activities as normal.
4. You will also receive a copy of the British Lung Foundation Keep Active Exercise Booklet which contains low level physical activity that can be safely incorporated into everyday life.

Group 2: Online exercise and support programme

This eight-week programme has three parts:

1. Online appointment

An hour long, individual video call with a SPHERE exercise specialist to assess and agree a level of exercise that is suitable for you.

2. Exercise at home

We will ask you to exercise at home at least twice a week. There are a few different ways you can do this:

- We will give you a **Participant Workbook** which includes general information about the SPHERE trial and pulmonary hypertension, a log to record the dates and times of your sessions, and some worksheets to use during the support sessions. This is a booklet with some simple exercises you can do safely at home. The booklet includes photographs of each exercise and instructions on how to do them. Videos of someone performing the exercises will also be available online. You can play these videos at home and follow at any time that suits you.
- We will also loan you an Exercise Bike and instruct you on how to use it safely. An online video will show you how to set it up and use it. Your SPHERE exercise specialist will create a simple exercise bike programme you can do at home.
- Attend a live online **group Exercise Session** once a week. These will last about 40 minutes. All sessions will be led by a SPHERE exercise specialist and will include exercises to help improve your fitness, strength, balance, coordination and mood. You will exercise at a level agreed by you and the specialist. You will be in a group of about eight people who are also taking part in the research study. Although there is only a very small risk of becoming unwell during exercise, we recommend that you have another person nearby at home when you are doing your first few exercise sessions.
- Each week, we will ask you to record what exercise you have done and how it made you feel on an exercise log. Your exercise specialist will call you each week to discuss how you are getting on and make any needed changes to your exercise level.

3. Online support group. You will be invited to attend six online group support sessions with the same people who are in your exercise group. These will last about an hour. During the sessions, your SPHERE exercise specialist will discuss problems with exercise and help you to recognise and overcome them. These sessions will help you get the most out of the SPHERE programme. If we

have any questions for you over the duration of the study, we will get in touch with you. Healthcare information held and maintained by NHS Digital and other Central UK NHS bodies, may be used to help contact you or to obtain information about your ongoing health status.

With your consent, we will observe and record your online appointment. For participants in Group 2 we will also observe and record your online exercise and support sessions. This is for quality control purposes and to provide the SPHERE team with an understanding of the topics and issues that generate discussion in the sessions.

For participants recruited in England (both groups), after your final assessment at 12 months, we will keep in touch with you by questionnaire. We will send you one very short questionnaire a year for the following four years. We will ask you to complete and return the questionnaires to us in a pre-paid envelope. The questionnaire should only take a few minutes to complete.

OPTIONAL- You do not have to agree to any of the following:

- 1. Interview:** With your consent, we may invite you to take part in an interview to explore your experience of being in the study and how it made you feel. If you tell us you are interested in this, we will send you a separate invitation email with an information sheet to help you decide.
- 2. Photographs and short video clips:** With your consent, we may take photographs or short video clips of the exercise sessions and support sessions to be used for conference presentations and publicity. If you agree to this, we will get in touch and arrange a suitable time.
- 3. Text messages:** With your consent we may contact you by mobile phone to remind you about appointments and to return questionnaires.

Do I need exercise equipment to take part in the study?

If you are assigned to the single online session of advice and support (Group 1), you do not need any exercise equipment. If you are assigned to the online exercise and support (Group 2) you will need an exercise bike to use at home. The exercise bike will be loaned to you for the eight weeks of the home exercise programme only. The SPHERE team will organise safe delivery directly with you directly and make sure it arrives fully assembled before your first online appointment. As such, your personal data (name and address) will be shared with a third-party bike loan or courier company. Your exercise specialist may also loan you a finger device for measuring your blood oxygen levels.

During your first online appointment, your exercise specialist will provide a tutorial on using the equipment safely at home. This tutorial will also be available to you online as a video. **If possible there should be another person nearby in your home when you are using the exercise bike.** If you are unable to have an exercise bike at home, you can still take part in the study. The use of the SPHERE exercise bike is for SPHERE participants only. Anybody else using the bike does so at their own risk.

Do I need a computer to take part in the study?

You will need internet access, an email address and use of an electronic device to make video calls and attend the online group exercise classes. This can be a smartphone, tablet, laptop or computer. The device needs to have a camera that faces you, so we can see you during the video call. For those who do not have the right equipment, we may be able to loan you a tablet for the duration of the home exercise programme.

We will use video call for the first appointment and for the exercise and support sessions. The study team will be available to help you with the use of computers, tablets, phones and other devices for video calls. A frequently asked questions (FAQ) sheet will be available by post or online.

What should I expect from an online group exercise session?

The online group exercise and support group sessions will take place via a third-party online video platform. If you are allocated to the eight week exercise and support programme, the SPHERE exercise specialist will provide you with a link to this website and ask you to register an account. The website will ask you to read and agree to the terms and conditions, then register an account using your name and email address.

During the online group sessions you will be visible on screen to the SPHERE exercise specialist and the other people in the group. You can choose to remain anonymous by creating a nickname to be displayed in place of your real name. You will be asked to complete some brief online questions before and after each group exercise session. This will allow the SPHERE exercise specialist to collect information on your health. Any data collected in this way will be encrypted and stored safely to NHS Digital and UK Government standards.

What are the benefits of taking part?

This research study may not offer you any direct benefit, but the results may will help people with pulmonary hypertension in the future. If any of our assessments find anything unusual with your health, you will receive prompt and appropriate medical care and attention.

What are the risks of taking part?

We do not anticipate any serious risk to you. There is always a very small chance that exercise can make you feel unwell. You will be advised and monitored by specialist staff. Exercise may cause tiredness, breathlessness and sore muscles, but this should get a bit easier each time you exercise. Although unlikely, if you are unwell during the live exercise sessions, a SPHERE exercise specialist will contact you immediately online or by telephone and send emergency medical help if needed.

Although there is only a very small risk of becoming unwell during exercise, we recommend that you have another person nearby at home when you are doing your first few exercise sessions. Sometimes, people can find the support sessions upsetting. Our specialist staff are fully trained and will provide appropriate support and assistance if needed.

What if new information becomes available?

Sometimes during a research study, new information becomes available about the treatment we are studying. If so, a researcher from Warwick Clinical Trials Unit will contact you to discuss your involvement in the study. If you decide to withdraw from the study, you should discuss your care with your doctor. If you continue in the study, you may be asked to sign an updated consent form if appropriate. We will use the SPHERE website to keep you updated on new information: www.warwick.ac.uk/SPHERE.

What if something goes wrong?

In the unlikely event that you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to cover associated costs. If you wish to complain about the study, or have concerns about the way you have been approached or treated during this study, please address your complaint to the person below, who is a senior University Hospitals Coventry and Warwickshire NHS Trust official entirely independent of this study:

Complaints Manager
University Hospitals of Coventry & Warwickshire NHS Trust
Clifford Bridge Road
CV2 2DX
Telephone no: 02476 965 198

For independent advice contact PALS (Patient Advice Liaison Service) on **0800 028 4203** or follow the NHS complaints procedure.

Will my taking part in this study be kept confidential?

All information we collect about you during the study will be kept strictly confidential and will only be accessible to authorised people. The only reason we would break confidentiality would be in an emergency. If your own health was in danger, we would contact your GP.

University Hospitals Coventry and Warwickshire NHS Trust (UHCW NHS Trust) is the sponsor for the study, based in the United Kingdom. The study will be managed by Warwick Clinical Trials Unit at the University of Warwick (UoW). UHCW NHS Trust and UoW will use information you provide and information from you, your medical records, central NHS and GP records to undertake this study and will act as joint data controllers. This means that, together, they are responsible for looking after your information and using it properly. UHCW NHS Trust and the UoW will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum amount of personally identifiable information possible. If you wish to

find out more about how we use your information, you can read the privacy statement on the UHCW and University of Warwick websites:

www.uhcw.nhs.uk/privacy

<https://warwick.ac.uk/services/legalandcomplianceservices/dataprotection/privacynotices/research/>

NHS sites will collect information from you and your medical records for this research study in accordance with our instructions. NHS sites, UHCW NHS Trust and UoW will use your contact details and next of kin details to contact you about the research study, to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from UHCW NHS Trust, the University of Warwick, and regulatory organisations may look at your medical and research records in order to invite you to the study and to check the accuracy of the data collected during the research study.

NHS sites will pass these details to UHCW NHS Trust and the UoW, along with information collected from you and your medical records. The only people at the UoW and UHCW NHS Trust who will have access to information that identifies you, will be people who need to contact you to book appointments, people who monitor your safety during group exercise sessions, people who follow up on your progress or regarding completion of questionnaires, people who host the database where your information will be stored, or people who will audit the data collection process. If we can't contact you, we may check local electronic hospital medical records, or contact your medical team or your next of kin. If you express an interest in participating in the study but are later deemed to be not eligible, your contact details will be disposed of securely.

The people who analyse the information will not be able to identify you and will not have access to your name or contact details. NHS sites will keep identifiable information about you from this study for a minimum of 10 years after the study has finished. If you agree to take part, your GP and other doctors who may treat you, but are not part of this study, will be notified that you are taking part in this study.

If you are allocated to the SPHERE online exercise and support programme group you will also be asked to register an account with a third party online video platform using your name and email address. This will enable you to access the online exercise and support sessions via Zoom. This online video platform will collect and store information on your attendance at classes, the number of times you have accessed on demand videos and any answers to online questions completed after the exercise sessions. This information will be stored alongside your name and email address. UoW and UHCW NHS Trust will be given access to this data to review your attendance and activity at sessions, use of online videos, and your safety. The data collected will be encrypted and stored safely to NHS Digital and UK Government standards until 12 months after the study has finished. Personal identifiable data stored by third parties will be securely deleted when it is no longer needed.

The University of Warwick and UHCW NHS Trust will collect information about you for this research study from you and your medical records. This information will include ethnicity, and health information, which is regarded as a special category of information. If you agree to take part, we may use anonymised data

collected for future research. Any future research will only proceed if approved by a Research Ethics Committee where necessary.

What will happen to the results of the study?

At the end of the study we will publish the findings in medical journals and at medical conferences. You will not be identified in any reports or publications. Once all participants have been followed up and the results have been analysed, we will make a copy of the study results available via an end of study information sheet and will add this to the study website: www.warwick.ac.uk/SPHERE. If you have specified that you would like to receive a copy of this information sheet, this will be sent to you.

Will I be reimbursed for taking part?

Your local travel to and from your three assessments for this study will be reimbursed up to £10 per return trip.

Who is organising and paying for the study?

This study is sponsored by University Hospitals Coventry and Warwickshire NHS Trust and is being coordinated by the University of Warwick. The study is being funded by the National Institute for Health Research, Health Technology Assessment programme (project number 17/129/02).

Who has reviewed the study?

Any research that involves the NHS and patients is subject to review by an independent group of people called a Research Ethics Committee. This committee is there to protect your interests. This study has been reviewed and given favourable opinion by Coventry & Warwickshire Research Ethics Committee. People with pulmonary hypertension have also been involved in every part of designing and setting-up this study.

Contact for further information:

If you have any questions about the study, either now or in the future, do please contact us using the details below:

Stuart Ennis (Research Fellow)

Tel: 02476 234 570

stuart.ennis@warwick.ac.uk

For independent advice contact PALS (Patient Advice Liaison Service) on **0800 028 4203**.

Thank you for taking the time to read this information and for considering taking part in this study.