Personalised Exercise-Rehabilitation FOR people with Multiple long-term conditions (multi-morbidity)

PERFORM Randomised Controlled Trial

Trial Participant Information Sheet

Principal Investigator: Professor Sally Singh

TRIAL SUMMARY

- You are being invited to take part in the PERFORM trial.
- You have been given this information sheet because you have 2 or more long-term health conditions.
  If you decide to take part in this trial you will be randomised to either the PERFORM rehabilitation programme group or the usual care (control) group. This is like tossing a coin, as there is a 50% chance of being in either group.
- The PERFORM rehabilitation programme runs for 8 weeks. This involves group-based exercise and health and wellbeing sessions, which are 2 hours long and take place twice a week.
- For those randomised to the usual care (control) group you will not get anything extra or attend the rehabilitation programme but your contribution will still be valuable and contribute to the results of the trial which may benefit patients in the future.
- This trial is testing whether the PERFORM rehabilitation programme improves the health and mood of people with multiple long-term conditions and whether it is cost-effective.
- We will ask you to come for 3 extra research visits at baseline, 3 months and 12 months. You will be asked to complete some questionnaires and some physical assessments at these visits.
- We are also conducting optional interviews as part of this research trial to find out your views on both the PERFORM rehabilitation programme.
- We are inviting 604 patients across the UK to take part.
- There are no guaranteed benefits to you taking part but you may contribute to the future healthcare of patients.

This information sheet will provide you with information about the trial. You do not have to take part. If you do agree to take part, then you are free to withdraw at a later date. You can find information on how to do this later in this information sheet.

You can also watch a short infographic video describing the trial, please use the QR code below or view on the PERFORM trial website: https://le.ac.uk/perform

Introduction

You are being invited to take part in a research trial. Before you decide whether or not to take part, it is important for you to understand why the research is being done, what it will involve, and what will be expected of you. Please take time to read this information sheet carefully and discuss with others if you wish. It is up to you to decide whether or not to take part. If you decide to take part you are still free to change your mind at any time during the trial. That decision will not affect the healthcare you receive.

If there is any part of this information sheet that you do not understand, or if you require further information, please contact us and we will be happy to answer any questions you have. Our contact details are on the back page.

What is the purpose of the research trial?

There is an increase in the number of people living with two or more long term conditions. Examples of long-term conditions are high blood pressure, diabetes, COPD (Chronic obstructive pulmonary disease), Osteoporosis, Asthma and Parkinson's Disease etc. This is partly due to people living longer. Living with two or more long-term conditions can be termed multi-morbidity or multiple long-term conditions. People living with multiple long-term conditions can experience reduced well-being (quality of life). They are more at risk of being admitted to hospital and dying at a younger age.

In people with one long-term condition, previous research has shown that undertaking a supervised programme of exercise-based rehabilitation can help people feel better and need less hospital admissions. Exercise rehabilitation aims to re-build muscle strength, increase walking and running endurance, and improve overall flexibility and mobility. These programmes are typically attended twice a week for a couple of hours for between 8 to 12 weeks long. However, in people with multiple long-term conditions we don't have a good understanding of how a rehabilitation programme will affect them or their different symptoms. Access to exercise-based rehabilitation programmes was identified as a priority by our patient and public involvement (PPI) representatives. A PPI group are patients or other people with relevant experience and long-term conditions who contribute to how a trial is designed, conducted and shared.

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

The PERFORM Randomised Controlled Trial will seek to recruit 604 participants from across the UK.

The PERFORM programme involves;

- A baseline assessment of your health needs looking at your starting fitness and health level and a medication review
- A structured programme of supervised exercise training
- Health and wellbeing sessions which provide you with support to manage common symptoms and aim to help you feel better
- A discharge appointment following the last session
- A home-exercise programme and progress tracker
- Check-in sessions 1 and 2

This trial will follow you up at 3 months and 12 months after you start the programme. This is to assess any short- and long-term changes. By looking at these changes we will compare whether the PERFORM personalised exercise-rehabilitation programme provides different results than the usual treatment (standard of care) a patient would receive through the NHS or another provider.

Why have I been invited to participate?

You have been invited to take part because you are over 18 years of age and have been identified as having multiple long-term health conditions. You will also have been identified as potentially benefiting from a personalised exercise rehabilitation programme. We want to offer you the opportunity to read about this trial and ask any questions.

Do I have to take part?

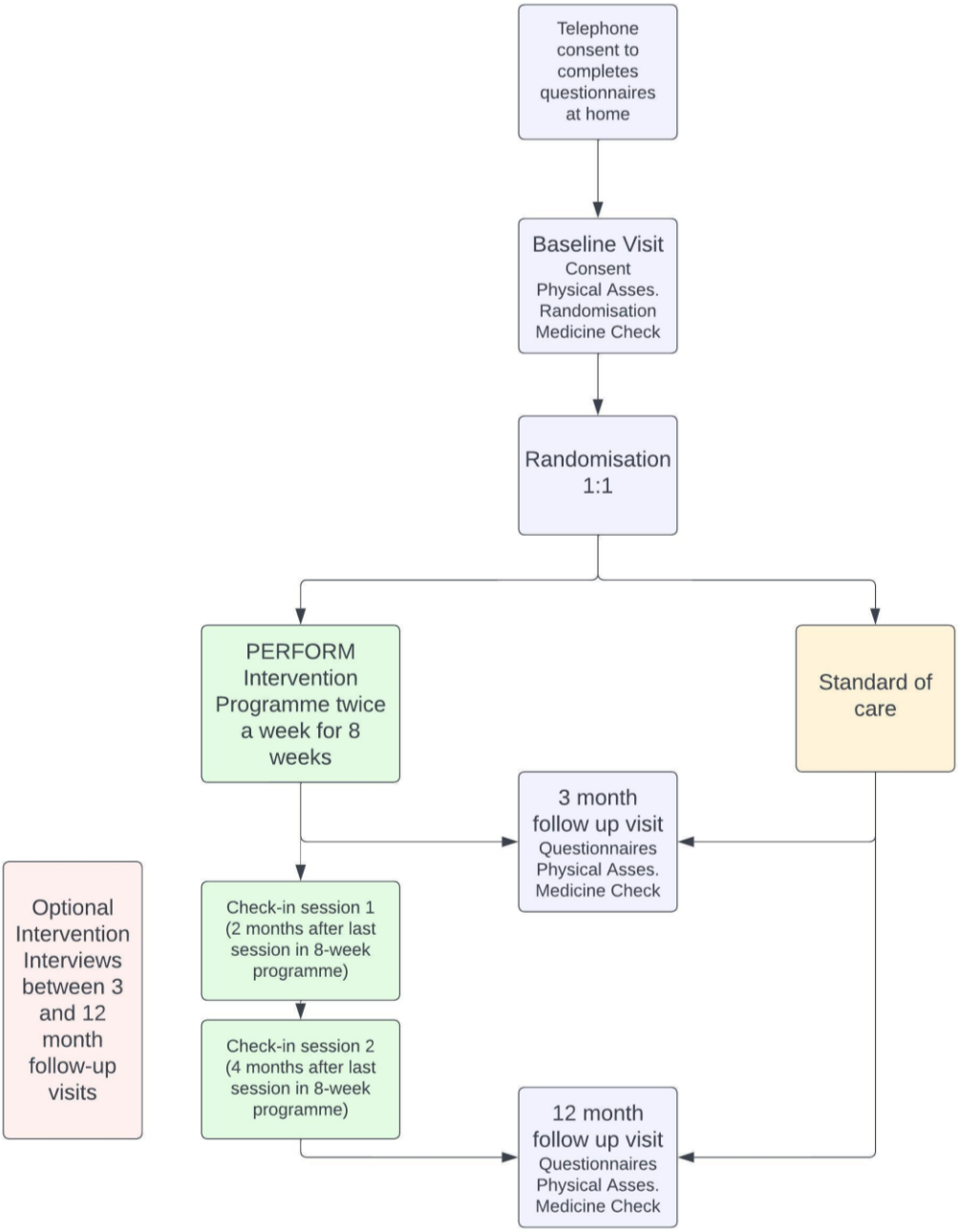
No, taking part in this trial is voluntary. If you do not wish to take part, this will not affect any ongoing care that you receive. If you do decide to take part but later change your mind, you are free to withdraw at any time. All you need to do is contact the research team/researcher using the information provided at the end of this document.

What will happen to me if I take part?

You will be given an appropriate amount of time to consider whether you would like to take part and the opportunity to ask any questions you may have. Following this a member of the trial team will go through the consent process with you at your first research visit and ask you to sign a consent form. You will be given a copy for your records. A letter will also be sent to your GP to let them know you are taking part in this trial.

As this is a randomised controlled trial your details will be put into an automated computer system. This will decide whether you are allocated to receive either the PERFORM rehabilitation programme plus your usual care or continue with your usual care only.

There is a one in two (50%) chance you will receive the PERFORM rehabilitation programme or a one in two (50%) chance you could be chosen to continue with standard of care (like the flip of a coin). These 2 groups are called the 'arms' of the trial.



Trial Visit Schedule

- Baseline Research Visit - lasts approximately 2 hours and will take place at your local trial site. You will be asked to complete all the trial assessments listed below. You will be given the option to consent over the telephone to completing the questionnaires in advance – there is a separate information sheet to explain this process.

- Randomisation to either PERFORM rehabilitation programme plus usual care or usual care only.
    - PERFORM Rehabilitation Programme – 2 sessions a week for 8 weeks. Each session lasts 2 hours and takes place at a exercise rehab clinic or gym facility
    - Usual care means you will attend all of your normal appointments for your existing conditions, but that you will not attend the PERFORM rehabilitation programme or another exercise rehabilitation programme.
- 3 month follow-up research visit - lasts approximately 2 hours and will take place at your local trial site. You will be asked to complete all the trial assessments listed below.
- PERFORM rehabilitation programme only – check-in sessions at 2-months and 4-months after your last session in the 8-week programme. Each session will last 2 hours and take place at an exercise rehab clinic or gym facility.
- 12 month follow-up research visit - lasts approximately 2 hours and will take place at your local trial site. You will be asked to complete all the trial assessments listed below.

Full details of the research visit assessments and the intervention are listed below.

Trial Assessments

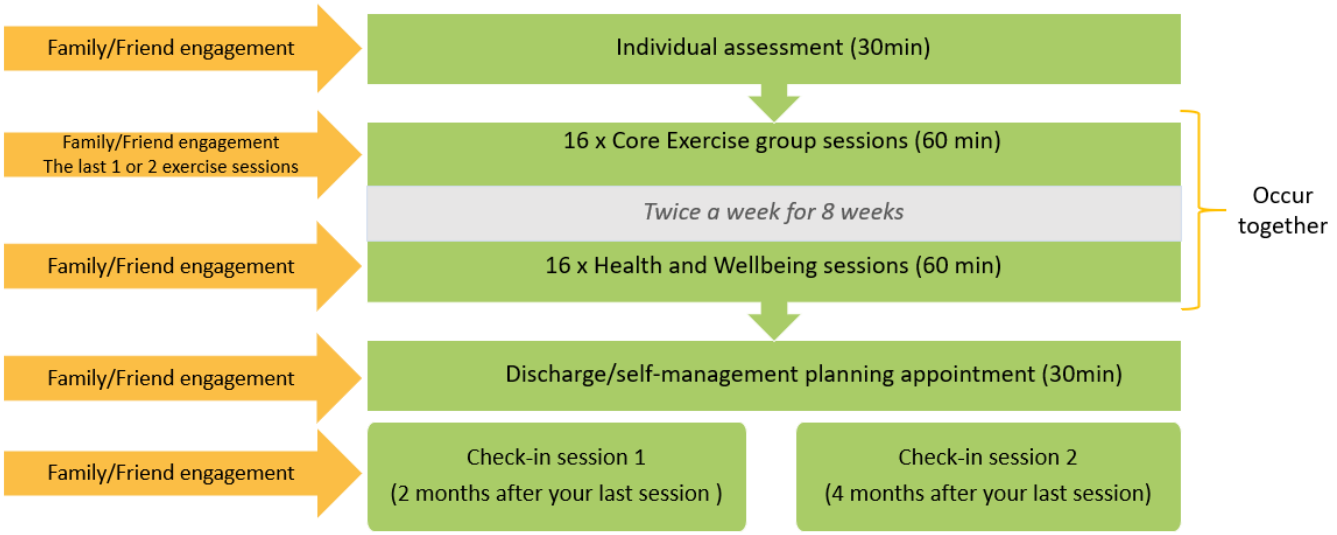
- Eligibility check (only at baseline)
- Consent to trial (only at baseline)
- Record your demographics details including:
  Date of birth, Gender, Ethnicity, Marital/civil partnership status, living situation, Smoking status, Address (postcode) Socio Economic Status by collecting details on education and employment status and & Caring responsibility
- Medicine check
- Medical History including details about your long-term conditions
- Vital signs (height, weight, resting blood pressure, resting heart rate and respiratory frequency)
- **Incremental shuttle walk test.**
  This test consists of walking around 2 cones set at 9 metres apart whilst keeping to the pre-set timings and ‘bleeps’, being played on a CD, you will be asked to do this for as long as you feel able. The walking speed increases as time goes on. The effect of walking on your heart and blood pressure will be monitored. You will be asked to wear light comfortable clothes and shoes.
- **Endurance shuttle walk test.**
  This test consists of walking around 2 cones set at 9 metres apart whilst walking at a constant speed, you will be asked to do this for as long as you feel able. The effect of walking on your heart and blood pressure will be monitored. You will be asked to wear light comfortable clothes and shoes.

- **4 metre Gait walk speed test.**
  This test will time how long it will take you to walk 4 metres.
- **Muscle performance (hand grip strength)**
  You will be asked to grip a piece of equipment which will measure how much pressure (strength) you are able to exert. You will be asked to repeat this until we have three readings that are very similar.
- **Questionnaire completion**
  We will ask you to complete a number of questionnaires. You will be given the option to complete these questionnaires in the comfort of your own home before the visits or to complete them at the in-person visits. There is an additional information sheet to give your further details. If you decide to complete the questionnaires at home you will be asked to confirm this choice over the telephone. Most of these questionnaires are short and individually take only a few minutes to complete. In total, they may take between 30-60 minutes to complete. They will be about your symptoms and how they affect your day-to-day activities and how you feel physically and mentally. All the questionnaires are already used in different areas of health. Please be aware that some of the questionnaires are assessing similar areas and the same type of questions may be asked in in slightly different ways. A member of the research team will be there to answer any questions and help you where needed. The PHQ-9 and the GAD-7 questionnaires have some questions that are on sensitive subjects. Even if you are completing these questionnaires at home, support is still in place for sensitive questions by contacting the research team or your GP. Alternatively, you can take a break and resume completing them with the support of the researcher at site at your in-person visits.

The PERFORM Rehabilitation Programme

The PERFORM programme has 2 sessions a week for 8 weeks -this is 16 sessions in total. This is a supervised rehabilitation programme that will be offered at a local health care setting. Each session will last for 2 hours - 1 hour for the 'move and improve' exercise component and 1 hour for the accompanying 'Health and Wellbeing' self-care session.

We encourage family, friend and carer engagement throughout the PERFORM rehabilitation programme. Further details are listed below and in a separate information sheet.



Initial Individual Assessment

Before you begin the programme, you will have an assessment with a member of the research team. This will look at whether you have any injuries or pain, and ask about how much and what sort of exercise you may do currently. It will cover your symptoms, mental and physical health and is done so that the team can give you a personalised exercise programme. This will take place after the baseline assessment, will last for up to 30 minutes and a family member, friend or carer may be present with you during this conversation.

Twice weekly sessions -Move and Improve Hour

This hour will have a gentle warm up, different exercise 'stations' with aerobic and strength components and a cool down. Exercises may include walking at different speeds, knee lifts, wall pull-ups, practicing sitting-to-standing and will depend on your personally prescribed programme. Several PERFORM facilitators will be on hand to answer your questions They will also make sure you are safe and getting the most out of each session. There will be approximately 4-10 other people with different long-term conditions attending each class. There might be differences in the type and intensity of exercises between different participants, this is because PERFORM is customised to a person's unique needs.

Twice weekly sessions - Health and Wellbeing Hour

This hour will be a presentation and then a group discussion on a different topic each session. The topics include healthy eating, the benefits of exercise, stress management and relaxation techniques, managing pain, better sleep, making the most of your medicines, and stopping worsening of symptoms. The person leading the session will offer advice and support for behaviour change to support positive lifestyle changes and symptom management. You will be provided with a workbook to aid with your action planning during the sessions. All participants can invite a

family member, friend or carer to accompany them to the health and wellbeing group sessions. This means that people who are not patient participants in the programme may be in attendance. If you would like your family member, friend or carer to attend then there is a separate information sheet for them to read and a consent form to sign.

Home Exercise Programme

You will also be encouraged to complete a home exercise programme that will be designed alongside your PERFORM Rehabilitation Programme visits by the trial team. This will be closely monitored by the trial team for your progress and activities. You will be given a booklet of exercises that can be done easily at home and a progress tracker. These exercises will be similar to those prescribed during the sessions and include side steps, knee lifts, feet tap backs, pull-ups and side-raises with small weights. There will be options to do these exercises whilst standing or sitting.

Discharge appointment

After the PERFORM Rehabilitation Programme finishes you will be asked to complete an end of programme discharge form. This will look at supporting you with long-term goals and ways to continue exercising. This will take place immediately after your last session in the 8-week programme, and a family member, friend or carer may be present with you during this conversation.

Check-in sessions 1 and 2

About 2 months and 4 months after your last session in the 8-week programme you will also be given the opportunity to attend 2 check-in sessions. These sessions will provide an opportunity to review your long-term progress and address any further questions you may have. They will follow the same format as the previous sessions with an exercise hour and a health and wellbeing hour.

Standard of Care Participants

If you are randomised to the standard of care group of this trial, nothing will change regarding your current treatment plan with your individual medical providers. If you have on-going or new health needs these will still be managed by the relevant teams. You will be invited to attend the baseline initial research visit and the 3- and 12-month follow-up visits only.

Optional Interviews

We would like to invite you to take part in an optional additional interview if you are randomised to the PERFORM Rehabilitation Programme. If you consent to being approached for this optional interview then researchers from the University of Glasgow will contact you after your 3-month follow-up visit and provide you with an

information sheet. This separate information sheet will give you the full details on the interviews and why the Glasgow team want to hear about your experience of taking part in the PERFORM rehabilitation programme. You will be given the opportunity to review the information and if you agree to being interviewed about the rehab programme the researcher will go through consent statements with you and sign the form on your behalf. This optional interview will be conducted by the team in Glasgow via videocall or over the telephone and will be recorded.

Fidelity Assessment and Recordings
Part of this trial will be checking if the PERFORM Rehabilitation Programme is delivered as originally intended. This is called fidelity. This will involve observations by trial team members and sound recording some of the rehabilitation programme visits (exercise and Health and Wellbeing sessions). These will not be recorded without your consent, and your consent to these are optional. The team conducting the analysis of these recordings will only require a specific number of each session to be recorded, this means that even if you consent to being recorded you may not be.

What are the possible benefits of taking part?

The PERFORM rehabilitation programme is aimed to help people manage their multiple long term health conditions. You may experience some benefit in taking part. However, as this intervention is being tested these benefits are not guaranteed. The information we learn may help in caring for other patients in the future.

If you decide to take part, we will inform your GP with your permission. If any results from the tests undertaken as part of the trial are clinically significant, we will inform both you and your GP, who will act accordingly. Otherwise, you and your GP will not receive the outcome of any test or assessment.

What are the possible disadvantages and risks of taking part?

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.
We don't expect you to be harmed in any way by taking part in our trial, but you could experience some discomfort when you complete the walking assessments. If you are randomised to take part in the PERFORM Rehabilitation programme this will involve exercise, so there is a risk that you might initially have muscle soreness. Your facilitator will make sure that the starting level of exercise is appropriate for you and you will be monitored at all times by a Health Care Professional who will also ensure you are doing the exercises correctly. You may also be exposed to sensitive matters of discussion such as participants life experiences and symptoms during the health and wellbeing sessions.

What if something goes wrong?

If you have a concern about any aspect of this trial, you should ask to speak with a member of the trial team who will do their best to answer your questions. If you have concerns about any aspect of the way you have been approached or treated during the course of the trial, you may wish to contact the hospital's Patient Advice and Liaison Service (PALS). Contact details for the research team and PALS office can be

found below. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from the PALS office or from the hospital.
It is very unlikely that you would be harmed by taking part in this type of research trial. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against University of Leicester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).
If you wish to make a complaint, or require advice about taking part in the trial you can contact the Patient Information and Liaison Service (PILS).

Patient Information and Liaison Service contact information:

- **Phone number:** 08081 788337
- Email address: pils.complaints.compliments@uhl-tr.nhs.uk

Will I be reimbursed?

We will offer up to £10 reimbursement for travel expenses for each of the three main research visits (baseline, 3 and 12 month follow up) with proof of purchase provided (receipts, bus tickets, etc.). These payments will be managed with your trial contact at the visit.

Will my participation be kept confidential?

While you are taking part in the trial, your contact details will be made available to the researchers so that they can contact you to arrange the details of your research trial appointments. On the consent form, you can also choose to be informed about the results of the trial. If you consent for this to happen, we will store your contact details securely, separately from your clinical information, and we will only use them for the purposes you have chosen. Your contact details will be destroyed once they have been used for the purpose that you have agreed to. We take confidentiality very seriously.

You should be aware that we have a professional and ethical duty to act on concerns for your safety and welfare. If we identify welfare issues, such as deteriorating illness or concerns of abuse, we may need to report these to your GP, your hospital team, or social services. We will tell you if we do this. If for any reason you lose capacity or you choose to withdraw from the trial, we will continue to use the information we have already collected towards the research analysis.

How will we use information about you?

We will need to use information from you, from your medical records, and your GP for this research project.

This information will include your

- Initials
- NHS number
- Name
- Contact details
- Address

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. This is called pseudonymised data.

The University of Leicester is the sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:

- The University of Leicester will act as data controller for this trial.
- All data collected as part of this trial will be treated with the strictest confidence and in accordance with legal and ethical requirements for data storage.
- All data collected will be stored in securely locked filing cabinets and in password protected databases
- Any data accessed by authorised individuals from the Sponsor, regulatory authorities, the host NHS organisation for monitoring or audit purposes will be pseudonymised.
- Any data accessed by the collaborating partners of this trial including researchers at the University of Birmingham, Glasgow, Salford, Exeter, York and Trinity College Dublin will be pseudonymised.

International transfers

We may share data about you outside the UK for research related purposes to:

- Combine pseudonymised data with our Australian collaborators for the purposes of a pooled analysis with their data.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Monash University, Melbourne Australia

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following

- the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of **6** years. The study data will then be fully anonymized and securely archived or destroyed.

What are your choices about how your information is used?

- you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records / your

hospital / your GP at the 3-month and 12-month follow-up timepoints. If you do not want this to happen, tell us and we will stop

- you have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- our leaflet [www.hra.nhs.uk/patientdataandresearch]
- by asking one of the research team
- by sending an email to the University of Leicester's Data Protection Officer on dpo@le.ac.uk, or
- by contacting us on performLCTU@le.ac.uk

What will happen to the results of the research trial?

A copy of the findings of the research trial will be offered to you through a newsletter and/or dissemination of webpage link should you agree to this on the consent form.

The results of this trial will be used to inform about future wide-spread roll-out of the intervention. We will review how recruitment goes, the results of the assessments completed (the physical tests done at the baseline and follow-up visits) including the questionnaires. The results will also be published in academic journals and presented at conferences and other meetings, as well as used in discussion with policymakers regarding the current and future rehabilitation programmes offered within the NHS.

What should I do if I want to take part?

If you are interested in taking part, please let one of the research team know during your visit, via the contact information at the end of this information sheet or by using the reply slip.

You will be asked to complete an Informed Consent Form and to opt-in to a variety of research options by placing your initials within the Yes or No box. This will confirm you understand how your data will be processed, protected and reviewed for research purposes.

Who is organising and funding the research trial?

This is a research trial funded by the National Institute for Health Research UK Research and Innovation (NIHR) and sponsored by the University of Leicester. The

Leicester Clinical Trials Unit are overseeing the organisation and management of the trial.

Who has reviewed the research trial?

This trial has been reviewed by South Central - Berkshire BREC and has received a favourable ethical opinion. Favourable ethical opinion means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision.

The trial has also been reviewed by the University of Leicester, as well as an independent Patient Advisory Group which comprises members of the public.

Patient Advisory Group Involvement

We are continually looking for ways we can involve patients in our research and particularly those who have taken part in the PERFORM Rehabilitation Programme. If you are interested in becoming a patient advocate and joining the PERFORM Patient Advisory Group then please indicate this choice on the consent form and your contact details will be passed on.

Thank you for taking the time to read this information and consider taking part in this research

For further information or to contact the research team, please see below.

James Manifield / Emily Morgan-Selvaratnam

- Email address: perform2@leicester.ac.uk
- Phone number: 0116 258 3113