



## Participant Information Leaflet

# PERCS

## Personalised Exercise Rehabilitation in Cancer Survivorship

### You are invited to take part in a research study

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully. Discuss it with friends and relatives if you wish.

### Main points to know:

- The **Personalised Exercise Rehabilitation in Cancer Survivorship (PERCS)** study is looking at how to support people who have had cancer treatment to take part in exercise-based rehabilitation.
- We are inviting suitable individuals to attend St James's Hospital for an appointment with a physiotherapist, who will assess your physical and psychological wellbeing. They will then

provide advice about what kind of exercise could help you in your recovery.

- This research is funded by the **Irish Cancer Society** and is run by a team of healthcare professionals and researchers in **Trinity College Dublin** and **St James Hospital**.

### Parts of this information leaflet:

1. About the study
2. Data protection
3. Costs, funding & approval
4. Future research
5. Further information

### If you would like to take part in this study, or have any queries, contact us:

Dr Louise Brennan, PERCS Project Manager

**Email:** percs@tcd.ie

**Phone or text:** 087090 2644 / 01 896 4809

## Principal

<b>Investigator:</b>	Dr Emer Guinan	Assistant Professor, Trinity College Dublin
<b>Co-investigators:</b>	Dr Louise Brennan	PERCS project manager, Research Fellow, Trinity College Dublin
	Dr Sonya Collier,	Principal Clinical Psychologist, St James Hospital
	Dr Amy Dennett	Clinical Researcher, La Trobe University
	Dr Deirdre Connolly	Associate Professor, School of Occupational Therapy, Trinity College Dublin
	Dr Claire Donohoe,	Consultant Surgeon, St James Hospital
	Dr Suzanne Doyle	Assistant Professor, Technological University of Dublin
	Cathy Enright	Clinical Advisor, Trinity St James's Cancer Institute
	Prof Juliette Hussey	Discipline of Physiotherapy, Trinity College Dublin
	Niamh Murphy	Physiotherapy Manager, St James's Hospital
	Linda O'Neill	Research Fellow, Trinity College Dublin
	Dr Maria Pertl	Lecturer in Health Psychology, RCSI
	Sarah Wade	Clinical Specialist Physiotherapist, St James Hospital

## Part 1 – The Study

### Why is this study being done?

Each person experiences the negative side effects of cancer treatment differently. Symptoms like pain, weakness, low energy, anxiety or depression can last long after the treatment ends. This can make recovery from cancer feel difficult, both physically and psychologically.

Evidence shows that exercise can help manage many of the side effects of cancer. Healthcare professionals worldwide recommended that cancer survivors take part in regular exercise to manage symptoms and look after their general health.

The COVID-19 pandemic was a challenging time to undergo cancer treatment. During this time, people experienced additional stresses, isolation and uncertainty. Additionally, because of lockdowns and stresses on healthcare systems, rehabilitation services and activities were difficult to access. Many people with cancer felt that their mental and physical wellbeing were affected during this time.

**Therefore, we are running a study with people who had cancer treatment since the beginning of the COVID-19 pandemic. We will assess their physical and psychological wellbeing and make recommendations for what type of exercise-based rehabilitation will suit each person.**

## Why am I being asked to take part?

We are asking you to take part because you had treatment for cancer in St James Hospital between March 2020 and May 2022.

## Do I have to take part? What happens if I say no? Can I withdraw?

You are free to decide whether or not to take part in this research study. Take time to decide. If you choose not to take part, this will not affect your future treatment or care.

If you choose to take part, you can change your mind and leave at any time, even if the study has started. You can contact Louise Brennan, PERCS project manager, to organise this for you. Email: [percs@tcd.ie](mailto:percs@tcd.ie)

## How will the study be carried out?

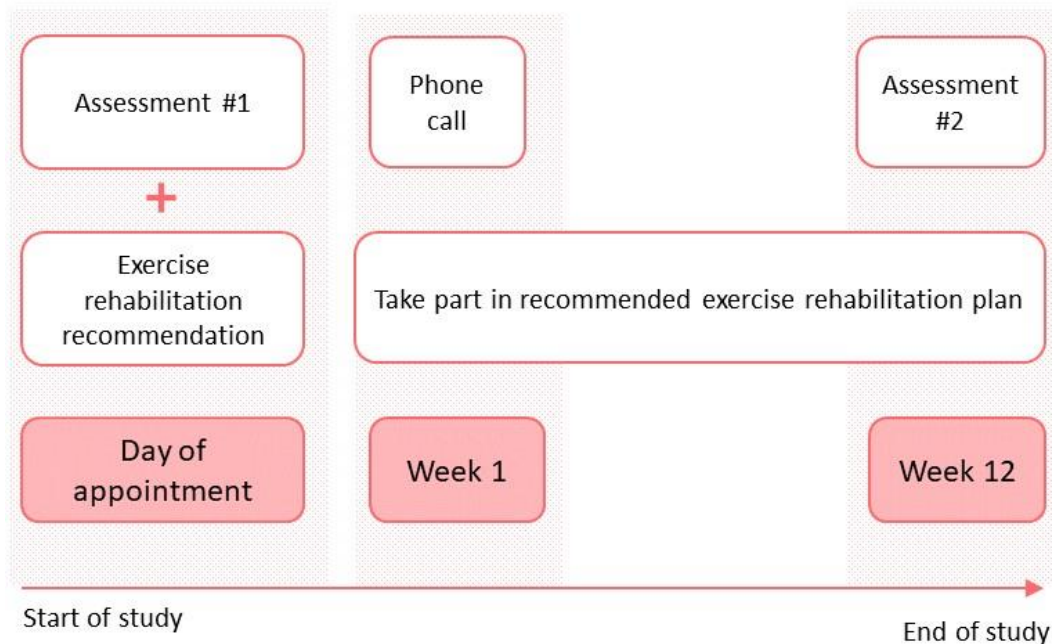
If you decide to take part, you will receive an appointment for an assessment in St James Hospital. Before this appointment, you will complete some questionnaires about your current symptoms.

**At your appointment**, you will meet a physiotherapist, who will ask you questions about your recovery from cancer and how you are managing both physically and psychologically. This will include:

- Discussion of your medical history and current symptoms
- Discussion of your current abilities and activity levels
- Discussion of your goals related to your recovery from cancer
- Physical assessment: strength, walking ability and other tests of your physical function

**After this assessment**, the physiotherapist will assign you to one of three exercise rehabilitation options, depending on your abilities:

1. **If you are already physically active:** you will be advised to continue your current exercise routine.
2. **If you need to improve your activity levels:** the physiotherapist will work with you to identify a suitable local exercise programme or facility which is run by a fitness professional. We will discuss this with you, to make sure it is a form of exercise that you will enjoy and can access. We will direct you to where and how you can do this type of exercise. If there is a cost to attend the programme, we will cover this cost.
3. **If you need extra support from a healthcare professional to become more active:** you will be referred to see a specialist physiotherapist.



All participants will be advised to visit a website we have developed which has information to support people in becoming active after cancer treatment.

**One week after the assessment,** a member of the research team will telephone you to provide support in starting the recommended exercise programme.

**Twelve weeks after the assessment,** you will have a second assessment in St James's Hospital. A random selection of participants will also be invited for a short one-to-one interview to get patient feedback on the PERCS study.

### What will happen to me if I agree to take part?

You can decide if you would like to take part or not. If you would like more information before deciding, please the project manager, Dr Louise Brennan via email: [percs@tcd.ie](mailto:percs@tcd.ie) or phone: 087 090 2644 / 01 896 4809

**If you decide to take part,** we will ask you to sign a consent form to say you are happy to be part of this study.

You will be then be invited to an assessment at the Wellcome Trust-HRB Clinical Research Facility at St James's Hospital, Dublin. The assessment is described on page 3 of this leaflet.

A plan for exercise-based rehabilitation will be recommended, as described on page 3. We will ask you to follow this recommendation for 12 weeks to the best of your ability.

### **Are there any benefits to me or others if I take part in the study?**

As exercise is shown to improve health and reduce symptoms after cancer treatment, you may experience these benefits.

By taking part in this study, you will be helping the PERCS research team collect evidence for how useful this system of connecting people with exercise and rehabilitation services is. If we find that the system is helpful, we will recommend that it is continued as part of normal care after cancer, with modifications based on participant feedback and our findings.

### **Are there any risks to me or others if I take part in the study?**

We do not expect there to be any disadvantages to taking part in this study. There are some risks associated with exercise, such as injuries and cardiovascular incidents. To minimize this risk, we will discuss your medical history and ensure there is no medical reason why you should not exercise. For those who are medically safe to exercise, it is widely accepted that the benefits of exercise outweigh the risks and we will recommend exercise that is safe for you.

### **What will happen if something goes wrong when I'm taking part in the study?**

Your safety during the study is very important to us. All study assessments will be carried out by expert researchers in the Clinical Research Facility at St James's Hospital.

If you experience any adverse effects during or after the study assessments or exercise sessions, you should stop exercising and tell your GP, a member of the research team or, if it applies, the person leading the exercise session

### **Will I be told the outcome of the study? Will I be told the results of any tests or investigations performed as part of this study that relate to me?**

Results from this study will be shared with healthcare professionals at an education day and will be presented to management at St James Hospital and to the National Cancer Control Programme (NCCP). We will also present results at conferences and publish a scientific paper describing the study in a medical journal.

The researcher doing your assessment will discuss the results of your assessment with you. Any findings from the assessment that would impact directly or indirectly on your health will be reported to you.

## Part 2 – Data Protection

### **What information about me (personal data) will be used as part of this study? Will my medical records be accessed?**

As part of this study, we will collect the following information about you:

- Age
- Gender
- Height and weight
- Details of your cancer and cancer treatment
- Past medical history
- Medications you take
- Other details about your life, such as your occupation, level of education, and whether you smoke or drink alcohol

We will also collect information from your assessments on your physical abilities and mental wellbeing.

### **What will happen to my personal data?**

**Coded data:** We will assign a code to identify you, and all of your data will be labelled with this code, instead of your name. This protects your data and makes it hard to identify any particular participant.

**Identifiable data:** A small amount of information we collect could potentially be used to identify you (**'identifiable' data**). We will store this data in a secure password protected database and locked cabinets at the Trinity Centre for Health Sciences at St James's Hospital Dublin. This identifiable information will never be shared with anyone outside of the research team.

**If you choose to leave the study,** any data which has already been collected will be kept for use in this research study, unless you request it not to be used. We will not collect any more data from you after you leave. Data will be stored for up to 10 years. We follow EU data protection laws (GDPR 2018) to protect your data to a very high standard.

## **Who will access and use my personal data as part of this study?**

Members of the PERCS research team will access and use your personal data as part of this study. All team members have data protection training. The study data controllers are: Trinity College Dublin and St James's University Hospital.

## **Will my personal data be kept confidential? How?**

We will take many steps to make sure that we protect your identity and data during the study. A Data Protection Impact Assessment has been completed to minimise any potential risks to your data.

## **What is the lawful basis to use my personal data?**

The lawful basis for processing of your personal data is covered by Article 6(1)(e) and Article 9(2)(j) of GDPR.

Article 6(1)(e) states processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.

Article 9(2)(j) states that processing is necessary for scientific research purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

## **What are my rights?**

You have the following rights regarding your data:

- Right to access data held
- Right to restrict the use of the data held
- Right to correct inaccuracies
- Right to have information deleted
- Right to data portability

## Part 3 – Costs, Funding & Approval

### **Will it cost me anything if I agree to take part?**

It will not cost you anything to take part. The research team will cover any parking fees at attend assessments at St James's Hospital. If you are referred to an exercise service which has a cost, we will cover that cost.

### **Who is funding this study? Will the results study be used for commercial purposes?**

This study is funded by the Irish Cancer Society. The results will not be used for commercial purposes.

### **Has this study been approved by a research ethics committee?**

The study has been approved by the St James Hospital / Tallaght University Hospital Joint Research Ethics Committee (researchethics@tuh.ie).

## Part 4 – Future Research

### **Will my personal data and/or biological material be used in future studies?**

If you consent to sharing your data for the benefit of other studies, it may be used in future studies about rehabilitation in cancer. The data will be 'coded' and you will not be able to be identified. Any future study wishing to use your data will be first approved by a research ethics committee.

You can give us your consent to use your data for all future research, or if you prefer, we can contact you each time we wish share your data outside of the St. James's Hospital/Trinity College Dublin research team.





## Part 5 – Further Information

### Where can I get further information?

If you would like to take part in this study, or have any questions, please contact **Dr Louise Brennan**, the PERCS project manager

**Email: [percs@tcd.ie](mailto:percs@tcd.ie)**

**Phone: 087 090 2644 / 01 896 4809**

You can also contact the Principal Investigator, **Dr Emer Guinan**:

**Email: [guinanae1@tcd.ie](mailto:guinanae1@tcd.ie)**

You can contact the Data Protection Officer via email: [dataprotection@stjames.ie](mailto:dataprotection@stjames.ie)

### What happens if I wish to make a complaint?

If you have a complaint about this study, contact the Principal Investigator, Dr Emer Guinan. Complaints about data protection should be made to the Data Protection Officer at Trinity College Dublin (email: [dataprotection@tcd.ie](mailto:dataprotection@tcd.ie)).

### Will I be contacted again?

We will telephone you to follow up on this invitation and answer any questions you may have about the study.

The research team may wish to contact you in future, particularly about taking part in new studies. In the consent form you can choose if you would like to be contacted for this purpose or not.

**Thank you for taking the time to read this information leaflet. Please contact us if you would like to find out more or would like to take part in the PERCS study.**