



ST. JAMES'S HOSPITAL

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PARTICIPANT INFORMATION LEAFLET

Rehabilitation Strategies following Oesophagogastric and Hepatopancreaticobiliary Cancer (ReStOre II)

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|--------------------------------|--------------------------|-------------------------------------|
| Principal Investigator: | Prof Juliette Hussey | Professor in Physiotherapy |
| Co-investigators: | Prof John V Reynolds | Professor of Surgery |
| | Dr Annemarie Bennett | Assistant Professor |
| | Prof Kevin Conlon | Professor of Surgery |
| | Dr Deirdre Connolly | Associate Professor |
| | Dr Suzanne Doyle | Assistant Professor |
| | Mr Justin Geoghegan | Consultant Surgeon |
| | Dr Emer Guinan | Assistant Professor |
| | Dr Peter Knapp | Reader in Health Sciences |
| | Prof Charles Normand | Emeritus Professor |
| | Dr Linda O'Neill | Project Manager |
| | Prof Jacintha O'Sullivan | Professor in Translational Oncology |
| | Dr Ricardo Seguardo | Associate Professor |

You are being invited to take part in a research study. Before you decide whether or not you wish to take part, you should carefully read the information provided below. Please take your time to make your decision. You may wish to discuss this with your family, friends, or healthcare team. If you have any questions, you can ask a member of the research team. You should clearly understand the risks and benefits of participating in this study so that you can make a decision that is right for you.

PART 1 – THE STUDY

Why is this study being done?

The purpose of this study is to investigate the effect of a rehabilitation programme on functional performance in people who have completed treatment for cancer of the oesophagus (food pipe), stomach, pancreas or liver. Functional performance describes the ability to carry out normal activities such as walking or household tasks. Treatments for cancer of the oesophagus, stomach, pancreas and liver such as chemotherapy, radiotherapy or surgery may alter normal functional performance. At St. James's Hospital we have been completing research over the past number of years to measure the change that may occur in functional performance during cancer treatment. This information has been used to inform the design of a rehabilitation programme (ReStOre) which includes exercise, diet and education sessions aimed at improving functional performance and well-being for people who have completed treatment for cancer of the oesophagus/ stomach/ pancreas/liver.



Why am I being asked to take part?

People who have completed treatment for cancer of the oesophagus/stomach/pancreas/liver are being asked to take part.

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

No, it is up to you to decide whether or not you take part.

If you decide to take part, you will be asked to sign the consent form. You will be given a copy of this information sheet and a signed consent form for you to keep.

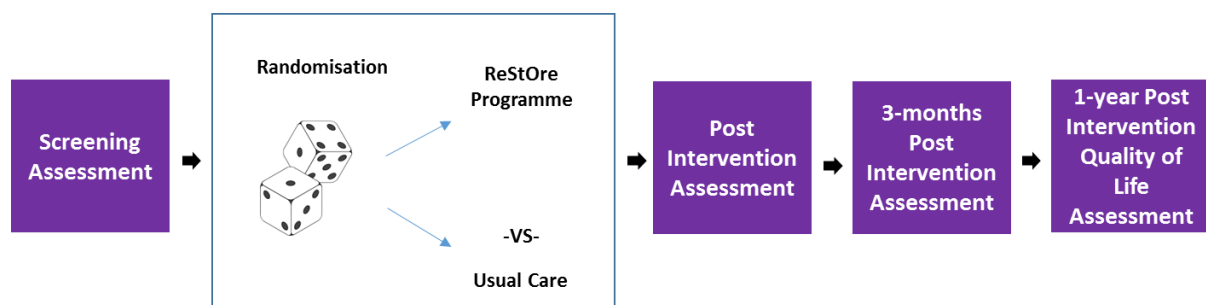
You will still be free to leave the study at any time, with or without giving a reason. If you decide to leave the study, this will not affect your future treatment and care.

If you wish to opt out, please contact the project manager Dr Linda O'Neill (email: exerciseoncology@tcd.ie, telephone: 01 8964809), who will be able to organise this for you.

How will the study be carried out?

This study began in spring 2022. A total of 120 participants will be recruited. The study will take place at St James's Hospital Dublin. This study will take the form of a **randomised controlled trial**. A randomised controlled trial is a very high-quality form of research when participants who share a particular characteristic (i.e. oesophageal/stomach/pancreas/liver cancer treatment) are randomly assigned to receive either a new treatment or the standard of care. In this way researchers can compare the outcomes between the two groups and decide if the intervention had any effect.

In this study participants will be randomly assigned to participate in either the intervention group or the control group. The **intervention group** will undertake the **ReStOre programme**. The **control group** will continue with their **usual hospital care**.



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

If you decide to join the study you will be asked to attend the Wellcome Trust-HRB Clinical Research Facility at St James's Hospital, Dublin for a screening assessment. The assessment components are detailed below.



Physical Performance

- You will perform an **exercise test** to calculate your physical fitness. This test will be performed on a stationary bike. The test will require you to exercise on a stationary bike until exhaustion. You will wear a face mask and have a pin prick blood test taken during the test. The test will last approximately 6-10 minutes. During the test you will be monitored by a physiotherapist/exercise physiologist and a doctor.
- Your strength will be measured with a **hand grip test**, and a **leg press test**.
- You will perform a **short battery of physical tests**, including a balance test, walking speed test, and repeated stands from a chair.
- You will be given a **physical activity** monitor to wear at home for one week to measure the amount of activity you do.

Body Composition

- We will measure your **height, weight** and **waist circumference**. Waist circumference measures the amount of weight on your stomach using a measuring tape.
- We will measure your body composition using a Seika bio-impedance machine.

Dietary intake

- You will **discuss** your **diet** with the study dietitian to highlight specific issues and complete some questionnaires to capture your normal eating pattern.

Quality of Life

- You will be required to complete **questionnaires** about your quality of life and symptoms such as fatigue.

As part of the screening assessment, we will also collect information about your medical history. The total time needed to complete this assessment is 90 minutes. These assessments will be repeated on two further occasions; post-intervention and three months post-intervention. We will also ask you to complete the quality of life questionnaires again after one year.

Randomisation

If you successfully complete the screening assessment you will be officially enrolled on to the study and will be randomly assigned to one of the two study groups.

1. Intervention Group – ReStOre Rehabilitation Programme

If you are randomly assigned to the intervention group you will attend a **rehabilitation programme** for 12 weeks at the Clinical Research Facility at St James's Hospital. Sessions will last approximately one hour and will take place twice per week for the first four weeks, once weekly from week 5-8 and then once per fortnight during the last four weeks. The programme will involve exercise, nutrition advice and education. You will complete 14 sessions over the 12 week programme, 8 of which will be in person at the Clinical Research Facility but you may choose to complete the other 6 sessions remotely via videocall.



ReStOre Rehabilitation Programme 12 weeks

Week 1-4
Twice per week

Week 5-8
Once per week

Week 9-12
Once per fortnight

Exercise

- Exercise programme prescribed to suit your fitness levels and supervised by a physiotherapist
- Supervised sessions and home-based programme

Nutrition

- Nutrition advice tailored to suit your individual needs prescribed and delivered by a dietitian
- Group discussion of common nutrition issues.

Education

- Group education sessions to address a range of issues experienced by cancer survivors delivered by a range of medical staff including doctors, physiotherapist, dietitian, and occupational therapist.

Participant Feedback

It is important that we gather your feedback on the ReStOre programme. We will gather your feedback on two occasions. Immediately after the ReStOre programme we will ask you to take part in a group discussion called a **focus group**. This focus group will take part during the last scheduled education session. Then after three-months we will invite you back to take part in a 1:1 interview.

What is a Focus Group/ 1:1 interview and what will we discuss?

A focus group is a group of people who come together to discuss a particular topic or to provide feedback on a service. In this case, people who participate in the ReStOre programme will be asked to come together to discuss the programme and provide feedback to the research team.

During the **focus group** you will discuss various aspects of the ReStOre programme. You will discuss the impact that the ReStOre programme may have had on your physical fitness and your ability to do your daily tasks. In addition we will seek your opinion on the structure of the ReStOre programme and suggestions for improving it. At the follow-up 1:1 interview we will discuss how you have been since completing the programme and if you have maintained the healthy lifestyle adaptations made during ReStOre e.g. diet, exercise etc.



The research team will make an **audio-recording** of the discussions. You will have access to the transcripts of your discussions if you wish and you can request change to be made to your personal comments if you are unhappy with the content. The focus group and interview will be led by a researcher not involved in the delivery of the ReStOre programme. This will allow you to speak freely and independently.

2. Control Group- Usual Care

If you are randomly assigned to the control group you will continue with your usual hospital care. You will attend the study assessments only.

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

If you take part in the study and share your medical information, you may help scientists and doctors understand the importance of rehabilitation after major cancer surgery. This may improve treatment for patients with cancer in the future. By participating in the exercise programme, you may benefit from the experience of taking regular exercise.

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

We do not anticipate adverse effects during the assessments or exercise sessions. You will only be invited to join the study if your doctors feel that you are well enough to participate in this programme.

During the exercise test you will have your blood lactate assessed via a pin prick assessment. This may cause slight pain but there will be no lasting harm and will only take a moment. This blood sample is minimal and will not be stored.

Occasionally people can feel dizzy or breathless when doing an exercise test. However because the exercise test is carefully graded and monitored by a physiotherapist/exercise physiologist and doctor, the risk of this happening are minimal. You may also feel a little tired after the exercise test, but this should pass quickly.

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

Your safety while taking part in the study is most important. All study assessments and intervention sessions will be carried out by researchers with expertise in this area. The Clinical Research Facility where all sessions will be performed have trained medical professionals on site, and is covered by the hospital emergency team. All study appointments will follow Covid-19 precautions.

In the event of you becoming unwell during an exercise assessment or class you will be evaluated and referred for appropriate treatment. If you experience any adverse effects as a result of the study assessments or exercise programme it is important that you inform a member of the research team immediately.



Will I be told the outcome of the study?

When the study is complete participants and their families will be invited to an information evening in which the overall results of the study will be presented.

Results will also be shared with healthcare professionals at an education day hosted by the research team. Overall findings will also be presented at relevant conferences and published in relevant peer-reviewed journals.

PART 2 – DATA PROTECTION

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

The following **clinical data** will be recorded at your first assessment. Access to your healthcare records will be required to gather this information.

- Age
- Gender
- Height and weight
- Information related to cancer diagnosis
- Past medical history
- Medications
- Cancer diagnosis
- Cancer treatment
- Smoking status
- Education
- Alcohol intake
- Dietary intake

Study data also includes information collected during your assessments; exercise test results, physical performance measures, body composition, quality of life, and focus group discussions. We will also record how individuals adhere to the exercise programme (e.g. number of sessions completed etc.).

What will happen my personal data?

We collect your data and use it in two ways;

- **Identifiable:** We store the electronic information that can identify you in a secure password protected database at the Trinity Centre for Health Sciences at St James's Hospital Dublin. We store signed consent forms in locket cabinets at the Trinity Centre for Health Sciences at St James's Hospital. This identifiable information is not shared with those outside of the research team.



- **Coded:** When you enrol on the study you will be assigned a unique code identifier. All of your study results will be stored under this code identifier.

If you choose to withdraw from the study, unless you state otherwise, any of your data which have been collected whilst you have been in the study will be retained for use in this research study. We will not collect any further data from you after you withdraw.

Data will be stored for up to 20 years. The law on data protection means we have to protect your data to a very high standard (GDPR, 2018).

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

Members of the ReStOre II research team will access and use your personal data as part of the study. Research team members will only be granted access to your data when they have completed training in data protection.

Will my personal data be kept confidential? How will my data be kept safe?

Your privacy is important to us. We take many steps to make sure that we protect your identity during the study and keep your data safe.

- We store all paperwork in locked cabinets, in locked offices with restricted access.
- We password protect all electronic files with identifiable information on password protected Trinity College Dublin computers.
- We make every research team member do data protection training.
- We check data security policies with any other researchers outside our research team before we share data.
- We have completed a Data Protection Impact Assessment to minimise any potential data breach risks.
- Data security procedures are regularly reviewed by data protection officers.

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?

No, it will not cost you anything to take part. The research team will cover any parking costs incurred at St James's Hospital during the study.

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

This study is funded by the Health Research Board.

Has this study been approved by a research ethics committee?

Ethical approval has been granted by the Tallaght University Hospital/ St James's Hospital Research Ethics Committee (researchethics@tuh.ie) and from the St Vincent's Hospital Research Ethics Committee (sue.canny@ucd.ie and jacintha.mcmanus@ucd.ie).

PART 4 – FUTURE RESEARCH

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

Your data may be used in future studies, provided you are happy with this. We use your data in as many studies as possibly to get the most benefit from them. Research can take thousands of participants and many many years to get meaningful results. All future studies will be health related research linked to diseases of the gastrointestinal tract. All future studies will be first approved by the relevant research ethics committee.

You may give us your consent for future research once off, or if you prefer, we can contact you each time we share your data outside of the St. James's Hospital/Trinity College Dublin research team **(This may be multiple times a year)**.



PART 5 – FURTHER INFORMATION

Where can I get further information?

The best person to contact is the project manager. They work closely with the doctors in the hospital and the research team. They would be happy to give you any more information you may want about the study. They are most likely to respond to you the fastest.

The project manager for this study is;

Dr Linda O'Neill

Email: exerciseoncology@tcd.ie

Telephone: 01 8964809

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| Principal Investigator: | Professor Juliette Hussey | Email: jmhussey@tcd.ie |
| Data Controllers: Trinity College Dublin St James's University Hospital St Vincent's University Hospital Tallaght University Hospital | | |
| Data Processors: Trinity College Dublin ReStOre II Research Team Email: exerciseoncology@tcd.ie St James's Hospital Dublin St Vincent's University Hospital Tallaght University Hospital | | |
| Data Protection Officer, Trinity College Dublin | | Email: dataprotection@tcd.ie |

What happens if I wish to make a complaint?

Complaints regarding this study should be directed to the Principal Investigator Professor Juliette Hussey. Complaints regarding data protection should be directed to the Data Protection Officer at Trinity College Dublin (dataprotection@tcd.ie).

Will I be contacted again?

You will be contacted again if you want to know every time your data are used in new studies. If something arises while you are taking part in this study, including anything which may affect your care, your Consultant will be informed immediately.

The research team may wish to contact you in the future. In particular they may wish to contact you with regards participation in new studies. In the consent form you will be explicitly asked to consent to receiving information about new research studies.