



St. James's Hospital
James's Street
Dublin 8

The RESTORE II study

Rehabilitation Strategies Following Oesophagogastric and Hepatopancreaticobiliary (HPB) Cancer

We invite you 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.
- 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.
- Ask us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information. If you decide to take part you will be given a copy of this information sheet and your signed consent form.

Important things you need to know

- The RESTORE II study is trying to find out the effect of a rehabilitation programme for patients who have had cancer of the food pipe (oesophagus), stomach, pancreas or liver.
- The rehabilitation programme lasts 12 weeks and is designed for patients who have completed their treatments.
- The programme includes exercise, education and advice on diet, and is delivered in small groups at St James's Hospital, Dublin.
- The RESTORE II study is a trial, comparing the rehabilitation programme with normal hospital care.
- You can stop taking part in the study at any time, without giving a reason.

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How to contact us

If you have any questions about the RESTORE II study, please contact:

Dr Linda O'Neill
RESTORE II project manager
Discipline of Physiotherapy
Trinity Centre for Health Sciences
St James's Hospital
Dublin 8

Email: exerciseoncology@tcd.ie

Phone: 01 896 4809

1 Why are we doing this study?

We are testing a rehabilitation programme for people who have completed their treatment for cancer of the food pipe (oesophagus), stomach, pancreas or liver.

We want to see if the rehabilitation improves people's ability to carry out normal activities such as walking or household tasks. Cancer treatment such as chemotherapy, radiotherapy or surgery can reduce people's ability to do these things.

At St. James's Hospital we have been studying the effects of cancer treatment for many years. In the first RESTORE study (2015 to 2017) we developed and tested the rehabilitation programme. The first RESTORE study showed that a programme of group sessions on exercise, diet and education could improve people's health and well-being.

We used the study results to develop the RESTORE II study. The RESTORE II study will include a much larger number of people, to give a clearer answer about the effects of the rehabilitation programme.

2 Why are you being asked to take part?

We are asking you to take part because you have completed treatment for cancer of the food pipe (oesophagus), stomach, pancreas or liver.

You do not have to take part, it is up to you to decide. If you decide to take part, you will be asked to sign the consent form. We would give you a copy of this information sheet and your signed consent form to keep.

If you decide to take part and later change your mind, you can leave the study at any time. You would not have to give a reason. If you did decide to leave the study, it would not affect your future treatment and care.

If you joined the study and then did want to leave it, please contact the project manager, Dr Linda O'Neill (email: exerciseoncology@tcd.ie or phone: 01 896 4809), who would organise it for you.

3 What do you need to know about the programme offered in this study?

This study will begin in Winter / Spring 2021/2022. The study will take place at St James's Hospital, Dublin and 120 participants will be recruited.

The RESTORE II study is a trial, sometimes called a randomised controlled trial or RCT. A trial is the best way to find out if a new treatment works.

People taking part in a trial will receive either the new treatment or the current, best treatment for their health condition. Which patients receive the new treatment or the current treatment is decided by random selection (by chance). This gives us the best information on whether the new treatment is better or worse than the current treatment.

In the RESTORE II study people taking part will be placed randomly in one of two groups: the intervention group or the control group. The intervention group will undertake the RESTORE rehabilitation programme. The control group will continue with their usual hospital follow-up.



The Intervention Group - RESTORE Rehabilitation Programme

Participants in the intervention group will attend a rehabilitation programme for 12 weeks at the Clinical Research Facility at St James's Hospital. Each session will last about an hour, usually in the middle of the day.

There will be two sessions each week for the first four weeks, then once weekly for the next four weeks, and then once every two weeks during the last four weeks.

There will be 14 sessions in all, 8 will take place face-to-face at the Clinical Research Facility but you may choose to do the other 6 sessions at home via videocall.

The programme will involve exercise, education and advice on your diet in a group of 4-8 people, all of whom have completed treatment for cancer of the food pipe (oesophagus), stomach, pancreas or liver.

RESTORE Rehabilitation Programme 12 Weeks

Weeks 1-4

Twice each week

Weeks 5-8

Once each week

Weeks 9-12

Once each fortnight

Exercise

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

Diet and Nutrition

- Diet and nutrition advice tailored to 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. These are delivered by various medical staff including doctors, physiotherapists, dietitian, and occupational therapist.

Feedback from participants in the Intervention Group

People in the intervention group will be asked for feedback on the RESTORE II programme. We will do this to hear what people think and if anything could be improved.

We will ask for your feedback twice. Firstly, at the end of the 12 week programme we will ask you to take part in a focus group discussion. This focus group will happen during the last education session. Secondly, three months later, we will invite you back for an individual interview.

In a focus group discussion a small group of people come together to discuss a topic. People taking part will discuss the RESTORE II programme and give feedback to the research team.

During the focus group you would discuss any impact the RESTORE II programme has had on your physical fitness and your ability to do daily tasks. We would also ask your opinion on the RESTORE II programme and how we could improve it.

At the individual interview we would discuss your health and well-being since the 12 week programme, and if you had been able to keep up any lifestyle changes that you had made, such as to diet or exercise.

The researchers would make an audio-recording of the focus group and individual interview. You could have access to the transcripts of your discussions if you wish. You could also request changes to your personal comments if you are unhappy with them.

The focus group and individual interview will be led by a researcher who is not involved in delivering the RESTORE II programme. This will allow you to speak freely and independently.

The Control Group - Usual Hospital Follow-up

People taking part in the control group in the RESTORE II study will continue with their usual hospital follow-up. You will attend for study assessments only.

Participants in both groups - the intervention and the control groups - will contribute to the success of the study.

4 What will you need to do if you take part?

If you decide to join the RESTORE II study you will be asked to attend the Wellcome Trust-HRB Clinical Research Facility at St James's Hospital, Dublin for an assessment. The assessment will last 90 minutes and is held to check that you are able to take part.

The details of the assessments are as follows:

a) Physical Performance

- We will test your physical fitness in an exercise test, using a stationary bike. The test will involve you exercising on a stationary bike until exhaustion. You will wear a face mask and have a pin prick blood test during the test. This bike test will last about 6-10 minutes. During the test you will be monitored and looked after by a physiotherapist or exercise physiologist, and a doctor.
- We will measure your strength with a hand grip test, and a leg press.
- We will also assess your standing balance, your walking speed, and your ability to stand up repeatedly from a chair.
- We will also ask you to wear a small physical activity monitor around your waist during your waking hours for a week, to measure how active you are.

b) Body Composition

- We will measure your height, weight and waist size.
- We will measure your body composition (including your body fat) using a Seika bio-impedance machine.

c) Diet

- You will discuss your diet with the study dietitian to highlight any specific issues. We will ask you to complete some questionnaires about your usual eating pattern.

d) Quality of Life

- We will ask you to complete some questionnaires about your quality of life and any effects of the cancer and its treatment, such as fatigue.

e) Medical history

We will ask you about your medical history.

Randomisation

If you complete the screening assessment and are fit to take part in the RESTORE II study, you will be randomly assigned to one of the two study groups, the intervention group or the control group.

If you agree to take part in the RESTORE II study, these assessments will take place on two more occasions, at the end of the 12 weeks rehabilitation programme and again three months after that. We will also ask you to complete the quality of life questionnaires one year after the end of the rehabilitation programme.

People in both groups in the RESTORE II study, the intervention and the control groups, will undertake the follow-up assessments and complete the follow-up questionnaires.

5 Possible benefits and disadvantages of taking part

Possible benefits

Taking part in the RESTORE II study may help scientists and doctors understand the role and importance of rehabilitation after treatment for major cancer. This could improve the treatment for patients with cancer in the future throughout the world. Participants in both groups, the intervention and the control groups, will contribute to the success of the study.

If you take part and are put into the intervention (rehabilitation) group, you may benefit from taking regular exercise and getting diet advice.

Possible disadvantages

We do not expect the assessments or exercise sessions to have any negative effects. You will only be invited to join the study if your doctors feel that you are well enough.

During the exercise test you will have a pin prick blood test. This may cause slight short-lasting pain but there will be no lasting harm. This blood sample is minimal and will not be stored.

Occasionally people can feel dizzy or short of breath when doing an exercise test. However the exercise test is carefully graded and you will be monitored by a physiotherapist or exercise physiologist, and doctor, so this is very unlikely. You may feel a little tired after the exercise test, but this should pass quickly.

What will happen if something goes wrong when you are taking part in the study?

Your safety during the study is most important. All study assessments and treatment sessions will be carried out by expert researchers. The Clinical Research Facility at St James's Hospital has trained medical professionals on site, and is covered by the hospital emergency team. All study appointments will follow Covid-19 guidelines.

If you did become unwell during an exercise assessment or treatment class you would be referred for any necessary treatment.

If you experience any adverse effects during or after the study assessments or exercise sessions, it would be important that you tell a member of the research team straight away.

6 Protecting your data

As part of the study we will use and collect some data about you. The following data will be recorded at your first assessment. We would need to access your healthcare records to gather this information.

- Age
- Gender
- Height and weight
- Information about your cancer
- Information about the treatment of your cancer
- Past medical history
- Any medications you take
- Your level of education
- Whether you smoke
- Whether you drink alcohol
- Your usual diet

We will also collect information about your assessments, (including the exercise test results, physical performance measures, body composition, quality of life questionnaires), and the focus group discussions. We will also record how many exercise sessions you attend.

What will happen to your personal data?

We collect your data and use it in two ways:

- **Identifiable:** We will 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 will store signed consent forms in locked 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 your 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 your personal data be kept confidential? How will your data be kept safe?

Your privacy is important to us. We will 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 your 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 your 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

Will your 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 possible to get the most benefit from them. Research can take thousands of participants and 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).

7 Further information about taking part

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.

This study is funded by the Health Research Board. The results will not be used for commercial purposes.

The study is led by the Principal Investigator:

- Professor Juliette Hussey, Professor in Physiotherapy at Trinity College, University of Dublin.

The study co-investigators are surgeons, physiotherapists, dietitians, occupational therapists, scientists and researchers:

- Professor John V Reynolds, Professor of Surgery, St James's Hospital and Trinity College, University of Dublin
- Professor Kevin Conlon, Professor of Surgery, Tallaght University Hospital, St Vincent's University Hospital and Trinity College, University of Dublin
- Mr Justin Geoghegan, Consultant Surgeon, St Vincent's University Hospital
- Trinity College, University of Dublin:
 - Dr Annemarie Bennett, Assistant Professor,
 - Dr Deirdre Connolly, Associate Professor,
 - Dr Emer Guinan, Assistant Professor,
 - Professor Charles Normand, Emeritus Professor,
 - Dr Linda O'Neill, Project Manager,
 - Professor Jacintha O'Sullivan, Professor in Translational Oncology
- Dr Ricardo Segurado, Associate Professor, University College Dublin
- Dr Suzanne Doyle, Assistant Professor, Technological University of Dublin
- Dr Peter Knapp, Reader in Health Sciences, University of York, UK.

The study has been approved by the Tallaght University Hospital and St James's Hospital Research Ethics Committee (researchethics@tuh.ie) and the St Vincent's Hospital Research Ethics Committee (sue.canny@ucd.ie and jacintha.mcmanus@ucd.ie).

When the study is complete all participants and their families will be invited to an information evening when the study results 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 conferences and published in medical journals.

8 Contacts for further information

The best person to contact is **Dr Linda O'Neill**, the project manager. She will work closely with the doctors in the hospital and the research team. She would be happy to give you any more information you may want about the RESTORE II study.

Dr Linda O'Neill can be contacted by email: exerciseoncology@tcd.ie or by phone (01 896 4809)

Alternatively you can contact the Principal Investigator, Professor Juliette Hussey (email: jmhussey@tcd.ie).

The study data controllers are:

Trinity College Dublin, St James's University Hospital, St Vincent's University Hospital and Tallaght University Hospital.

The study data processors are:

Trinity College Dublin, RESTORE II Research Team (email: exerciseoncology@tcd.ie), St James's University Hospital, St Vincent's University Hospital and Tallaght University Hospital

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

Will you be contacted again?

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

The research team may wish to contact you in future, particularly about taking part in new studies. In the consent form you will be asked if you give your consent to being sent information about new research studies.

This study is funded by the Health Research Board and led by the Principal Investigator, Professor Juliette Hussey, Professor in Physiotherapy at Trinity College, University of Dublin.

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