

# Use of physiotherapy to improve bowel function after rectal cancer surgery

<b>Submission date</b> 06/11/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 02/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/02/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English Summary

### Background and study aims

Up to 75% of patients experience difficulty controlling their bowels for up to 12 months following surgery for rectal cancer and 1 in 4 will continue to do so for more than a year. The introduction of an education session from specialist nurses and physiotherapists prior to surgery to teach patients how to improve their bowel function using a pelvic floor programme could be helpful. By assessing muscle tone in the pelvis before and after surgery to see if the introduction of pelvic floor training will determine if the programme is acceptable to patients and if they are able to comply with the programme at may be a stressful time for themselves and their family. In addition to evaluating the programme patients are interviewed to assess their satisfaction with the elements of the programme. This study is hoped to initiate further studies in future to look at the impact of introducing this intervention on bowel function and the effect on quality of life and function for bowel cancer survivors. The aim of this study is to test the feasibility of a simple intervention to improve bowel function following surgery for rectal cancer.

### Who can participate?

Adults aged 18 and older with rectal cancer.

### What does the study involve?

Patients recruited into this study are given an educational session to inform patients of bowel problems that can occur after surgery, simple measures to improve them and also education around pelvic floor exercises. Following this patients have an assessment of their pelvic floor by a physiotherapist and are given a tailored programme of exercises to follow for 12 weeks following their surgery, with two appointments at six and 12 weeks to assess progress. They are asked to complete questionnaires on quality of life and bowel function before surgery and after surgery (six and 12 weeks).

### What are the possible benefits and risks of participating?

Participants may benefit from increased education and the potential for improvements in bowel function after rectal cancer surgery. There are no direct risks to patients involved in the study.

### Where is the study run from?

1. Royal Glamorgan Hospital (UK)

2. University Hospital of Wales (UK)
3. Prince Charles Hospital (UK)

When is the study starting and how long is it expected to run for?  
September 2016 to October 2018

Who is funding the study?  
Tenovus (UK)

Who is the main contact?  
Mrs Julie Cornish

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mrs Julie Cornish

**Contact details**  
Department of Surgery  
Cwm Taf University Health Board  
Llantrisant  
United Kingdom  
CF728XR

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
2.0

## Study information

**Scientific Title**  
Physiotherapy and Anterior Resection Syndrome

**Acronym**  
PARiS

**Study hypothesis**  
The aim of this study is to test the feasibility of introducing a simple intervention in an attempt to improve bowel function following surgery for rectal cancer. We propose the introduction of an educational session from specialist nurses and physiotherapists prior to surgery to teach

patients how to strengthen their pelvic floor using this programme. The primary aim of this study is to see if the introduction of pelvic floor training is acceptable to patients and if they are able to comply with the programme at what may be a stressful time for themselves and their family.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Wales REC 6, 21/04/2016, ref: REC 16/WA/0124

### **Study design**

Feasibility non randomised study

### **Primary study design**

Interventional

### **Secondary study design**

Non randomised study

### **Study setting(s)**

Hospital

### **Study type(s)**

Quality of life

### **Participant information sheet**

Not available in web format, please use contact details to request patient information sheet

### **Condition**

Rectal Cancer

### **Interventions**

Participants undergo an educational Session and Pelvic Floor Rehabilitation programme.

Patients recruited into this study are given an educational session to inform patients of bowel problems that can occur after surgery, simple measures to improve them and also education around pelvic floor exercises. Following this participants have an assessment of their pelvic floor by a physiotherapist and be given a tailored programme of exercises to follow for 12 weeks following their surgery, with two appointments at six and 12 weeks to assess progress. They are asked to complete questionnaires on quality of life and bowel function before surgery and after surgery (six and 12 weeks).

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Proportion of eligible patients approached who consent and attend the educational session are measured using the screening log and attendance record at each site.

### **Secondary outcome measures**

1. Compliance with PFR programme is measured using Squeezy app +/-patient diaries for 12 weeks. Data will be collected at 6 and 12 weeks from the patients records
2. Acceptability of the intervention to the patient is measured using qualitative interviews for a proportion of patients (8-12) following the educational session and following the pelvic floor programme as 12 weeks
3. Pelvic floor tone measured using the Oxford Grading System, ICS grading system at the baseline assessment, 6 weeks and 12 weeks postoperatively
4. Patient bowel function is measured using LARS score and St Marks Faecal Incontinence Score at the baseline assessment, 6 weeks and 12 weeks postoperatively
5. Patient quality of life is measured using EQ5D, EORTC QLQ C30 and CR29, qualitative interviews at the baseline assessment, 6 weeks and 12 weeks postoperatively
6. Opinion on physiotherapy programme DVD are measured using focus groups following completion of the 12 week programme

**Overall study start date**

01/09/2016

**Overall study end date**

01/10/2018

## Eligibility

**Participant inclusion criteria**

1. 18 years old
2. Rectal cancer
3. Undergoing Anterior Resection procedure with planned intestinal continuity
4. Able to complete physiotherapy programme

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

40

**Total final enrolment**

9

**Participant exclusion criteria**

1. Unable to give informed consent
2. Not physically capable of performing the PFR programme

**Recruitment start date**

01/09/2017

**Recruitment end date**

01/09/2018

## **Locations**

**Countries of recruitment**

United Kingdom

Wales

**Study participating centre**

**Royal Glamorgan Hospital**

Llantrisant

United Kingdom

CF728XR

**Study participating centre**

**University Hospital of Wales**

Cardiff

United Kingdom

CF144XW

**Study participating centre**

**Prince Charles Hospital**

Gurnos Road

Merthyr Tydfil

United Kingdom

CF47 9DT

## **Sponsor information**

**Organisation**

Cwm Taf University Health Board

**Sponsor details**

Royal Glamorgan Hospital

Llantrisant

Wales

United Kingdom  
CF728XR

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/00rh52j13>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Tenovus

**Alternative Name(s)**

Tenovus Cancer Care

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high impact peer reviewed journal. Planned publication of the protocol.

**Intention to publish date**

30/09/2019

**Individual participant data (IPD) sharing plan**

The dataset generated during the study is available upon request until 01/03/2028. Anonymised demographic, medical, patient-reported outcome and study-specific metric data may be shared with bonafide researchers, for use in research projects carried out in the public interest within the context of medical care or treatment. Access requests are processed according to local NHS policy and procedure and access may be granted at the discretion of the Chief Investigator/ Data

Controller, who reserves the right to fully or partially withhold data. Further information, including application enquiries, should be made in writing to Mrs Julie Cornish at ColorectalResearch.CAV@wales.nhs.uk.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	30/06/2018	18/10/2019	Yes	No
<a href="#">Results article</a>		26/09/2022	24/02/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No