

# The feasibility of performing a walking programme in patients with rectal cancer undergoing chemo-radiotherapy (the REx trial)

<b>Submission date</b> 21/01/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/03/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/10/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-walking-programme-chemoradiotherapy-rectal-cancer-rex>

## Contact information

### Type(s)

Scientific

### Contact name

Miss Susan Moug

### Contact details

Level 5, Surgical Block  
Royal Alexandra Hospital  
Corsebar Road  
Paisley  
United Kingdom  
PA2 9PN  
+44 (0)141 314 6965  
[susanmoug@nhs.net](mailto:susanmoug@nhs.net)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

The REx Trial GN130N328

# Study information

## Scientific Title

A pilot study of the feasibility and patient-related outcomes of performing a walking intervention in patients undergoing treatment for rectal cancer (the REx trial)

## Study objectives

It is hypothesised that improving exercise capacity pre-operatively (pre-habilitation) by performing an individualised walking intervention will be feasible and lead to improvement in peri-operative psychological and physical health.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

West of Scotland Research Ethics Service (WoSRES), 22/04/2014, ref: 14/WS/0079

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Quality of life

## Participant information sheet

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

## Health condition(s) or problem(s) studied

Rectal cancer

## Interventions

The patients randomized to the walking group will have a consultation with the Project Co-ordinator (PC) where the walking intervention, including the use of the pedometer, will be explained with stepping count targets described. Pedometers have been used successfully by this research team and have been shown to be a motivational tool, which will increase walking in the short term and sustain walking over 12 months. The walking programme will consist of 15-17 weeks of intervention with the first 6 weeks consisting of graduated bi-weekly goals. The aim will be that walking behaviour is either maintained over the remaining weeks or

increased according to the individual. The goal is for the participants to increase their average daily step count by 3000 accumulated above their baseline value: based on the assumption that an adult walking at a moderate pace produces 100 steps/minute, an increase of 3000 steps on 5 days of the week would correspond to approximately 150 minutes of moderate physical activity over the course of the week, which is the recommended physical activity level for older adults in Scotland.

Control group: No walking intervention

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

1. To assess the feasibility of performing a walking intervention in patients with rectal cancer undergoing pre-operative chemo-radiotherapy.
2. How many patients can be recruited per month on average and what proportion of eligible patients are willing to be recruited?
3. Are patients willing to be randomised?
4. What is the initial retention and adherence levels that can be achieved for the programme in both interventional and control groups?
5. How many patients drop out of such a study and for what reasons?
6. Are patients able to carry out the intervention as planned and can it be successfully implemented?
7. How acceptable are the intervention, the delivery of, the duration of, the intensity of and the exit strategy to the participants?
8. What are the indicative cost implications of intervention delivery?

To assess primary and secondary outcomes, Tests 1 and 2 will be performed at two time points: pre-chemo-radiotherapy and post-chemo-radiotherapy/pre-surgery (referred to as Test 1 and Test 2, respectively). These tests include: feasibility measurements; body mass index, hip and waist circumference; sit-to-stand test, 6-minute walking test; sedentary time, active time, average steps walked per day. Psychological and quality of life will also be assessed at Tests 1 and 2 by: Becks Depression Inventory (BDI-II), FACT-C, PANAS, EORTC-QLQ C30. Peri-operative outcomes will be recorded during the patient's in-hospital stay post-surgery and for up to 30 days after surgery (length of hospital stay, length of level 2 stay, complications, time to medical discharge, mortality).

### **Secondary outcome measures**

1. Does pre-habilitation increase the number of steps walked per day?
2. Does pre-habilitation lead to improved recovery after surgery (in terms of time to step down from critical care; incidence of morbidity and time to discharge from hospital)?
3. Does pre-habilitation increase the average time spent per day in physical activity?
4. Does pre-habilitation decrease the average time spent per day in sedentary behaviour?
5. Does pre-habilitation lead to reduced fatigue and improved psychological and quality of life parameters?

### **Overall study start date**

01/06/2014

**Completion date**

01/06/2016

## Eligibility

**Key inclusion criteria**

1. Any patient over 18 years of age
2. Independently mobile
3. Has been diagnosed with rectal cancer
4. Planned first line of treatment is chemotherapy and radiotherapy followed by curative surgery (timing at discretion of surgeon, but expected between 10-12 weeks post-CRX)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

80

**Key exclusion criteria**

1. Chemotherapy and radiotherapy not first-line treatment
2. Patient has had previous malignancies
3. Significant co-morbidity where inclusion into this trial would put the patients health at risk
4. Patient has any mental, physical or psychological impairment that prevents them from giving signed informed consent
5. Patient is already achieving their recommended activity level per week where participation in a walking programme would mean he/she would be exercising at a lower level than normal

**Date of first enrolment**

01/06/2014

**Date of final enrolment**

01/06/2016

## Locations

**Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**  
**Royal Alexandra Hospital**  
Paisley  
United Kingdom  
PA2 9PN

## **Sponsor information**

### **Organisation**

NHS Greater Glasgow and Clyde (UK)

### **Sponsor details**

c/o Nathaniel Brittain  
Academic Research Co-ordinator  
Research and Development Central Office  
Tennent Institute  
38 Church Street  
Glasgow  
Scotland  
United Kingdom  
G11 6NT  
+44 (0)141 211 8544  
nathaniel.brittain@ggc.scot.nhs.uk

### **Sponsor type**

Hospital/treatment centre

### **ROR**

<https://ror.org/05kdz4d87>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

Chief Scientist Office (UK), ref.: CZH/4/984

### **Alternative Name(s)**

CSO

### **Funding Body Type**

Government organisation

## Funding Body Subtype

Local government

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	feasibility results	01/05/2019	21/01/2019	Yes	No
<a href="#">Plain English results</a>			20/02/2020	No	Yes
<a href="#">Results article</a>		01/09/2020	22/06/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No